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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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	• 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	• 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	• 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.

SCDM Certified Clinical Data Manager Sample Questions (Q126-Q131):

NEW QUESTION # 126
A Data Manager is establishing a timeline for database lock for a 100-person study where the data have been maintained almost all clean throughout the study. All data from external labs have been received and reconciled. Which is the best estimate of the amount of time needed to lock the database after Last Patient Last Visit?

- A. A few days
- B. A few hours
- C. A few weeks
- D. A few months

Answer: A

Explanation:
For a well-maintained 100-subject study with ongoing data cleaning and completed reconciliations, the database lock process typically takes a few days after the Last Patient Last Visit (LPLV).
According to the GCDMP (Chapter: Database Lock and Archiving), the duration of the lock process depends on the level of data cleanliness at LPLV. If the study team has conducted continuous data cleaning, query resolution, and external data reconciliation throughout the trial, then the final lock steps (e.g., final data review, documentation, and approvals) can be completed in 2-5 days. However, if significant cleaning or reconciliation remains outstanding, lock may take several weeks. Since the question states that data are "maintained almost all clean," Option B - a few days - is the appropriate estimate.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Lock and Archiving, Section 6.2 - Database Lock Preparation and Timelines ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Quality and Lock Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Lock and Archiving Procedures

NEW QUESTION # 127
All range and logic checks have been resolved in a study. An auditor found discrepancies between the database and the source. Which reason is most likely?

- A. Data were not abstracted correctly from the source
- B. The auditor made an error
- C. The discrepant data values were logical and in range
- D. Data were changed after the checks were run

Answer: A

Explanation:
Even when all range and logic checks are successfully resolved, discrepancies may still exist between the clinical database and the source documents. This typically indicates an error in data abstraction or transcription, meaning that data were incorrectly entered or extracted from the source records during the data entry or verification process.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), data validation rules such as range and logic checks are designed to identify inconsistencies, missing data, or out-of-range values within the database itself. However, they do not verify the accuracy of data entry against the original source documents - that responsibility falls under source data verification (SDV), typically conducted by clinical monitors or auditors.
When an auditor detects discrepancies between source and database values after all edit checks have passed, the most probable explanation is that data were not transcribed correctly from the source, rather than a failure in programmed edit checks. This could occur due to human error during manual data entry, misinterpretation of the source document, or oversight during SDV.

Option C (Data were changed after checks were run) might occur in rare cases but would normally be documented in an audit trail per 21 CFR Part 11 and ICH E6 (R2) standards. Option B misinterprets the issue, since "logical and in range" values can still be incorrect relative to the source. Option A (Auditor error) is possible but statistically less likely, as source data verification follows strict, documented audit procedures.
Therefore, the most likely reason for such discrepancies is Option D: Data were not abstracted correctly from the source, emphasizing the importance of robust data entry training, dual data entry, and verification procedures.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.5 - Source Data Verification and Reconciliation ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data Accuracy and Audit Trails
21 CFR Part 11 - Electronic Records and Electronic Signatures, Subpart B: Audit Trails and Record Accuracy

NEW QUESTION # 128
A study is collecting ePRO assessments as well as activity-monitoring data from a wearable device. Which data should be collected from the ePRO and activity-monitoring devices to synchronize the device data with the visit data entered by the site?

- A. Study subject identifier
- B. Geo-spatial location and study subject identifier
- C. Study subject identifier and date/time
- D. Geo-spatial location

Answer: C

Explanation:
To synchronize data from electronic patient-reported outcomes (ePRO) and wearable activity-monitoring devices with site-entered visit data, both the study subject identifier and date/time are essential.
According to the GCDMP (Chapter: Data Management Planning and Study Start-up), each dataset must contain key identifiers that allow for accurate data integration and temporal alignment. In studies involving multiple digital data sources, time-stamped subject identifiers are necessary to ensure that the device-generated data correspond to the correct subject and study visit.
The subject identifier ensures data traceability and linkage to the appropriate participant, while date/time allows synchronization of device data (e.g., activity or physiological measurements) with the corresponding site-reported visit or event. Geo-spatial data (options C and D) are typically not relevant to study endpoints and pose unnecessary privacy risks under HIPAA and GDPR guidelines.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Integration and eSource Data, Section 5.2 - Data Alignment and Synchronization Principles FDA Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, Section 4.2 - Data Linking and Synchronization ICH E6 (R2) GCP, Section 5.5.3 - Data Traceability and Integrity

NEW QUESTION # 129
The primary reason for system validation is to:

- A. Meet regulatory requirements.
- B. Allow a system to be used by its intended users.
- C. Fulfill the validation plan.
- D. Prove the system being tested works as intended.

Answer: D

Explanation:
The primary purpose of system validation in clinical data management is to demonstrate and document that the computerized system performs as intended-accurately, reliably, and consistently-throughout its lifecycle.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on System Validation) and FDA 21 CFR Part 11, validation ensures that all system functions (e.g., data entry, edit checks, audit trails, security) work as designed, providing data integrity, traceability, and regulatory compliance. The focus is on fitness for intended use, meaning the system reliably produces correct and reproducible results in the context of its operational environment.
While meeting regulatory requirements (option C) and fulfilling a validation plan (option B) are components of the process, they are not the ultimate purpose. The essential goal is ensuring that the system performs as intended, maintaining accuracy and data integrity for clinical trial operations.

Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Computerized Systems and System Validation, Section 5.2 - Purpose and Scope of System Validation
FDA 21 CFR Part 11 - Validation of Computerized Systems for Intended Use ICH E6(R2) GCP, Section 5.5.3 - Computerized System Validation and Data Integrity

NEW QUESTION # 130
Which Clinical Study Report section would be most useful for a Data Manager to review?

- A. Enumeration and explanation of data errors
- B. Description of statistical analysis methods
- C. Rationale for the study design
- D. Clinical narratives of adverse events

Answer: A

Explanation:
The section of the Clinical Study Report (CSR) that is most useful for a Data Manager is the one that includes the enumeration and explanation of data errors. This section provides a summary of the data quality control findings, including error rates, missing data summaries, and any issues identified during data review, validation, or database lock.
According to the GCDMP (Chapter: Data Quality Assurance and Control), post-study reviews of data errors and quality findings are essential for evaluating process performance, identifying recurring issues, and informing continuous improvement in future studies.
Other sections, such as clinical narratives (A) or statistical methods (C), are outside the core scope of data management responsibilities. The data error enumeration section directly reflects the quality and integrity of the data management process and is therefore the most relevant for review.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Quality Assurance and Control, Section 6.4 - Quality Reporting and Error Analysis ICH E3 - Structure and Content of Clinical Study Reports, Section 14.3 - Data Quality Evaluation

NEW QUESTION # 131
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