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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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	• 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 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	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q130-Q135):

NEW QUESTION # 130
In a physical therapy study, range of motion is assessed by a physical therapist at each site using a study-provided goniometer. Which is the most appropriate quality control method for the range of motion measurement?

- A. Comparison to the measurement from the previous visit
- B. Programmed edit checks to detect out-of-range values upon data entry
- C. Independent assessment by a second physical therapist during the visit
- D. Reviewing data listings for illogical changes in range of motion between visits

Answer: C

Explanation:
In this scenario, the variable of interest-range of motion (ROM)-is a clinically measured, observer-dependent variable. The accuracy and reliability of such data depend primarily on the precision and consistency of the measurement technique, not merely on data entry validation. Therefore, the most appropriate quality control (QC) method is independent verification of the measurement by a second qualified assessor during the visit (Option D).
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Quality Assurance and Control), quality control procedures must be tailored to the nature of the data. For clinically assessed variables, especially those involving human judgment (e.g., physical measurements, imaging assessments, or subjective scoring), real-time verification by an independent qualified assessor ensures that data are valid and reproducible at the point of collection. This approach directly addresses measurement bias, observer variability, and instrument misuse, which are primary sources of data error in clinical outcome assessments.
Other options, while valuable, address only data consistency or plausibility after collection:
Option A (comparison to previous visit) and Option C (reviewing data listings) are retrospective data reviews, suitable for identifying trends but not preventing measurement error.
Option B (programmed edit checks) detects only extreme or impossible values, not measurement inaccuracies due to technique or observer inconsistency.
The GCDMP and ICH E6 (R2) Good Clinical Practice guidelines emphasize that data quality assurance should begin at the source, through standardized procedures, instrument calibration, and dual assessments for observer-dependent measures. Having an independent second assessor ensures inter-rater reliability and provides direct confirmation that the recorded value reflects an accurate and valid measurement.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.4 - Measurement Quality and Verification ICH E6 (R2) Good Clinical Practice, Section 2.13 - Quality Systems and Data Integrity FDA Guidance for Industry: Patient-Reported Outcome Measures and Clinical Outcome

Assessment Data, Section 5.3 - Quality Control of Clinician-Assessed Data SCDM GCDMP Chapter: Source Data Verification and Quality Oversight Procedures

NEW QUESTION # 131
For ease of data processing, the study team would like the database codes for a copyrighted rating scale preprinted on the CRF. What is the most critical task that the CRF designer must do to ensure the data collected on the CRF for the scale are reliable and will support the results of the final analysis?

- A. Consult the study statistician regarding the change and determine that database codes will not influence the analysis.
- B. Consult the independent source of the rating scale for approval and document that continued validity of the tool is not compromised.
- C. Consult the independent source and determine database codes will not influence subject responses.
- D. Complete the requested changes to the instrument and ensure the correct database codes are associated with the appropriate responses.

Answer: B

Explanation:
When using a copyrighted or validated rating scale (e.g., Hamilton Depression Scale, Visual Analog Pain Scale), any modification to the original instrument, including preprinting database codes on the CRF, must be approved by the instrument's owner or licensing authority to ensure the validity and reliability of the instrument are not compromised.
According to the GCDMP (Chapter: CRF Design and Data Collection), validated rating scales are psychometrically tested tools. Any visual or structural modification (such as adding codes, changing layout, or rewording questions) can invalidate prior validation results. Therefore, the CRF designer must consult the independent source (copyright holder) for approval and document that the validity of the tool remains intact.
Merely consulting statisticians (option B) or verifying database alignment (option D) does not ensure compliance. Thus, Option C ensures scientific and regulatory integrity.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 6.1 - Use of Validated Instruments and Rating Scales ICH E6 (R2) GCP, Section 5.5.3 - Validation of Instruments and Data Capture Tools FDA Guidance for Industry: Patient-Reported Outcome Measures - Use in Medical Product Development to Support Labeling Claims, Section 4 - Instrument Modification and Validation

NEW QUESTION # 132
During a database audit, it was determined that there were more errors than expected. Who is responsible for assessing the overall impact on the analysis of the data?

- A. Investigator
- B. Quality Auditor
- C. Statistician
- D. Data Manager

Answer: C

Explanation:
The Statistician is responsible for assessing the overall impact of data errors on the analysis and study results.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Data Quality Assurance and Control) and ICH E9 (Statistical Principles for Clinical Trials), while the Data Manager ensures data accuracy and completeness through cleaning and validation, the Statistician determines whether the observed data discrepancies are statistically significant or if they may affect the validity, power, or interpretability of the study's outcomes.
The Quality Auditor (C) identifies and reports issues but does not quantify analytical impact. The Investigator (D) is responsible for clinical oversight, not statistical assessment. Thus, after a database audit, the Statistician (B) performs a formal evaluation to determine whether the magnitude and nature of the errors could bias results or require reanalysis.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Data Audit and Impact Assessment ICH E9 - Statistical Principles for Clinical Trials, Section 3.2 - Data Quality and Analysis Impact Assessment FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Validation and Analysis Review

NEW QUESTION # 133
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. The database set-up will need to be changed to allow for additional sites as they are added to the study.
- C. The distribution of subjects selected for quality control will need to be stratified to allow for the twelve new sites.
- D. Additional sites will likely have increased query rates since site training is occurring closer to study close.

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 # 134
Which of the following statements would be BEST included in a data management plan describing the process for making self-evident corrections in a clinical database?

- A. Self-evident corrections made in the database will be reviewed and approved by a team leader or manager.
- B. Self-evident changes may be made per the listed conventions and documented to the investigative site.
- C. A senior level data manager may make audited changes to the database without further documentation.
- D. No changes will be made in the database without a query response signed by the investigator.

Answer: B

Explanation:
A self-evident correction (SEC) refers to a data correction that is obvious, logical, and unambiguous - such as correcting an impossible date (e.g., 31-APR-2024) or standardizing a known abbreviation (e.g., "BP" to "Blood Pressure"). According to the Good Clinical Data Management Practices (GCDMP), SECs can be applied by data management staff following pre-approved conventions defined in the Data Management Plan (DMP).
The DMP should explicitly describe the criteria for SECs, including the types of errors eligible for this correction method, the required documentation, and the communication procedure to inform the investigative site. The process must maintain audit trail transparency and ensure that all changes are traceable and justified.
Options A and B suggest unauthorized or informal change procedures, which violate audit and compliance standards. Option C is too restrictive, as it prevents the efficient correction of non-clinical transcription or formatting errors.
Therefore, option D is correct: "Self-evident changes may be made per the listed conventions and documented to the investigative site." This approach aligns with CCDM expectations for balancing efficiency, accuracy, and regulatory compliance.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 6.2 - Self-Evident Corrections FDA 21 CFR Part 11 - Electronic Records; Audit Trails and Traceability Requirements

NEW QUESTION # 135
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