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SCDM CCDM Exam Syllabus Topics:

Topic	Details
Topic 1	• 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 2	• 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 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	• 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 5	• 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.

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SCDM Certified Clinical Data Manager Sample Questions (Q49-Q54):

NEW QUESTION # 49
Which of the following factors can be tested through a second test transfer?

- A. Transfer method
- B. Transfer frequency
- C. File format
- D. Change management

Answer: C

Explanation:
In the context of database design and external data management, a test data transfer (or trial data load) is performed to ensure the proper configuration, structure, and integrity of data imported from an external vendor or system. The second test transfer is specifically useful to confirm that data structures and formats are consistently aligned between the sending and receiving systems after initial adjustments have been made from the first test.
According to the Good Clinical Data Management Practices (GCDMP), the file format - including variables, data types, field lengths, delimiters, and encoding - must be validated during test transfers to confirm compatibility and ensure accurate loading into the target database. Once the initial test identifies and corrects errors (e.g., mismatched variable names or data types), the second transfer verifies that the corrections have been implemented correctly and that the file structure functions as intended.
Testing change management (A) involves procedural controls, not data transfers. The transfer method (C) and transfer frequency (D) are validated during initial process setup, not during subsequent test transfers.
Therefore, option B (File format) is correct, as the second test transfer verifies the technical integrity of the file structure before live production transfers begin.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers and Data Integration, Section 5.2 - Test Transfers and File Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Data Import and Validation Controls

NEW QUESTION # 50
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. Study subject identifier and date/time
- C. Geo-spatial location
- D. Geo-spatial location and study subject identifier

Answer: B

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 # 51
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. Programmed edit checks to detect out-of-range values upon data entry
- B. Reviewing data listings for illogical changes in range of motion between visits
- C. Comparison to the measurement from the previous visit
- D. Independent assessment by a second physical therapist during the visit

Answer: D

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 # 52
Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

- A. List of late queries by site and summary table
- B. Table of outstanding queries counts by site
- C. Graph of expected versus actual enrollment
- D. Graph and summary table of clean cases by site

Answer: A

Explanation:

The most effective information for addressing a backlog of unresolved queries at investigative sites is a list of late queries by site combined with a summary table.
According to the GCDMP (Chapter: Communication and Issue Escalation), timely and structured feedback to sites is critical for efficient query resolution. A detailed list of late or overdue queries, accompanied by summary statistics (e.g., counts, durations, status), enables data managers and monitors to prioritize follow-up actions, target problem areas, and provide focused support or retraining to underperforming sites.
While query count summaries (option B) are helpful for overview metrics, they lack the specific information (query ID, date, field, status) required for targeted follow-up. Graphs of enrollment or clean cases (options A and C) are unrelated to discrepancy resolution performance.
Thus, the combination of detailed lists and summarized performance metrics offers both granularity and a high-level overview - the optimal tool for query management communication.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 5.1 - Site Query Management Reports ICH E6 (R2) GCP, Section 5.18.4 - Communication Between Monitors and Sites FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Query Metrics and Site Performance Review

NEW QUESTION # 53
What action should a data manager take if an investigator retires in the middle of an EDC trial and the replacement does not agree to use EDC for the remainder of the trial?

- A. Explore other options for the site with the study team.
- B. Talk with the clinical research associate to identify alternative sites.
- C. Notify the project manager and request that the site be closed.
- D. Discuss the use of the site's data with the project statistician.

Answer: A

Explanation:
When an investigator retires mid-study and the replacement refuses to use the Electronic Data Capture (EDC) system, the data manager must not take unilateral action but rather collaborate with the study team to explore acceptable solutions.
Per the GCDMP (Chapter: Project Management in Data Management), any deviation from the established data capture method - particularly a change that affects regulatory compliance, data consistency, or site operations - requires a cross-functional assessment.
The study team, which includes clinical operations, project management, regulatory affairs, and data management, should evaluate feasible alternatives such as:
Allowing paper CRF entry followed by centralized data transcription,
Retraining site staff on EDC use, or
Temporarily suspending data entry until compliance can be restored.
Immediate site closure (option A) or unilateral decisions by data management (options C and D) violate escalation and communication protocols. Collaborative decision-making ensures continuity, compliance, and data integrity, in line with ICH E6 (R2) GCP and FDA 21 CFR Part 11.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 5.2 - Handling Site and Investigator Changes ICH E6 (R2) Good Clinical Practice, Section 4.1 - Investigator Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on EDC Operations and Site Management

NEW QUESTION # 54
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