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Section 1

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SCDM Certified Clinical Data Manager Sample Questions (Q30-Q35):

NEW QUESTION # 30
If a data manager generated no additional manual queries on data in an EDC system and the data were deemed clean, why could the data appear to be not clean during the next review?

- A. The study coordinator can change the data due to re-review of the source.
- B. The medical monitor can override safety information entered in the system.
- C. The data manager may have accidentally changed the data.
- D. The CRA can change the data during a quality review of source to database.

Answer: A

Explanation:
In an Electronic Data Capture (EDC) system, even after a data manager completes all manual queries and marks data as "clean," the data may later appear unclean if the site (study coordinator) makes subsequent updates in the system after re-reviewing the source documents.
According to the Good Clinical Data Management Practices (GCDMP, Chapter: Electronic Data Capture Systems), site users maintain the authority to modify data entries as long as the system remains open for data entry. The EDC system audit trail captures such changes, which can automatically invalidate prior data reviews, triggering new discrepancies or changing system edit-check statuses.
This situation commonly occurs when the site identifies corrections in the source (e.g., wrong date or lab result) and updates the EDC form accordingly. These post-cleaning changes require additional review cycles to ensure the database reflects accurate and verified information before final lock.
Options B, C, and D are incorrect - CRAs and medical monitors cannot directly change EDC data; they can only raise queries or request updates.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 6.3 - Post-Cleaning Data Changes and Audit Trails ICH E6 (R2) GCP, Section 5.5.3 - Data Integrity and Change Control FDA 21 CFR Part 11 - Electronic Records: Change Documentation Requirements

NEW QUESTION # 31
Which document contains the details of when, to whom, and in what manner the vendor data will be sent?

- A. Communication Plan
- B. Data Transfer Agreement
- C. Project Plan
- D. Data Management Plan

Answer: B

Explanation:
A Data Transfer Agreement (DTA) defines the operational and technical details for transferring data between a sponsor and an external vendor (e.g., central lab, ECG vendor). It is a formalized, controlled document specifying what data will be sent, when transfers will occur, the transfer method, file structure, encryption or security protocols, and the recipients of the data.
The DTA is developed jointly by the sponsor and vendor before production data transfers begin. According to the GCDMP, Chapter on External Data Transfers, this agreement ensures both parties share a clear understanding of timing, responsibility, and data content to minimize errors and ensure regulatory compliance.
The Data Management Plan (DMP) outlines general data handling processes but does not capture the technical specifics of vendor data transfer logistics. The Project Plan (A) and Communication Plan (B) are broader operational tools and not specific to data transfer protocols.
Hence, option C (Data Transfer Agreement) is the correct answer, as it precisely governs the procedural and technical framework of vendor data exchange.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: External Data Transfers, Section 4.1 - Data Transfer Agreements and Specifications ICH E6(R2) Good Clinical Practice, Section 5.5 - Trial Management, Data Handling, and Record Keeping

NEW QUESTION # 32
Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

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

Answer: B

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 # 33
There is a modification to the CRF and a sudden increase in the number of queries generated in the EDC system. Which action is most likely to reduce the number of queries?

- A. Introduce a source data verification process
- B. Have the monitor close the queries
- C. Review the edit checks for correctness
- D. Make some of the existing edit checks manually

Answer: C

Explanation:
When a CRF modification leads to a sudden increase in EDC queries, the most likely cause is an error or misconfiguration in the edit checks introduced during or after the change. Therefore, the first step should be to review the edit checks for correctness.
The GCDMP (Chapter: Database Design and Validation) emphasizes that any database or CRF modification should trigger retesting of affected validation rules. Incorrect logic, thresholds, or missing conditional statements in automated edit checks can cause false or redundant queries, leading to unnecessary data management burden and site frustration.
Manually handling edit checks (option A) or adding SDV (option B) does not address the root cause. Having monitors close queries (option D) would mask the problem rather than resolve it.
Thus, the correct corrective measure is Option C - review and validate the edit checks to ensure proper functionality.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Design and Validation, Section 5.5 - Edit Check Testing and Review ICH E6 (R2) GCP, Section 5.5.3 - Validation and Change Control for Electronic Systems FDA 21 CFR Part 11 - System Validation and Change Documentation

NEW QUESTION # 34
A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:
"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1." Which of the following is missing from the definition?

- A. Discrete values for a drop-down list
- B. Data type of the data element
- C. Enumeration
- D. Unit or dimensionality of measure

Answer: D

Explanation:
A complete data element definition in clinical data management should include:
Name and clear description of the data element,
Data type (e.g., numeric, text, date),
Precision or scale (if numeric), and
Unit or dimensionality of measure (e.g., centimeters, inches).
In this example, while the data type ("measured physical quantity") and precision (0.1) are defined, the unit of measurement (e.g., centimeters or inches) is missing. This omission leads to ambiguity and could cause serious discrepancies when comparing or analyzing measurements.
The GCDMP (Chapter: Database Design and Build) emphasizes that units and dimensionality must be explicitly defined and consistently applied in all CRFs, metadata dictionaries, and data transformations.
Thus, option D (Unit or dimensionality of measure) is correct.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Database Design and Build, Section 5.2 - Metadata and Data Element Definitions CDISC CDASH Implementation Guide, Section 3.3 - Data Element Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Data Accuracy and Standardized Definitions

NEW QUESTION # 35
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