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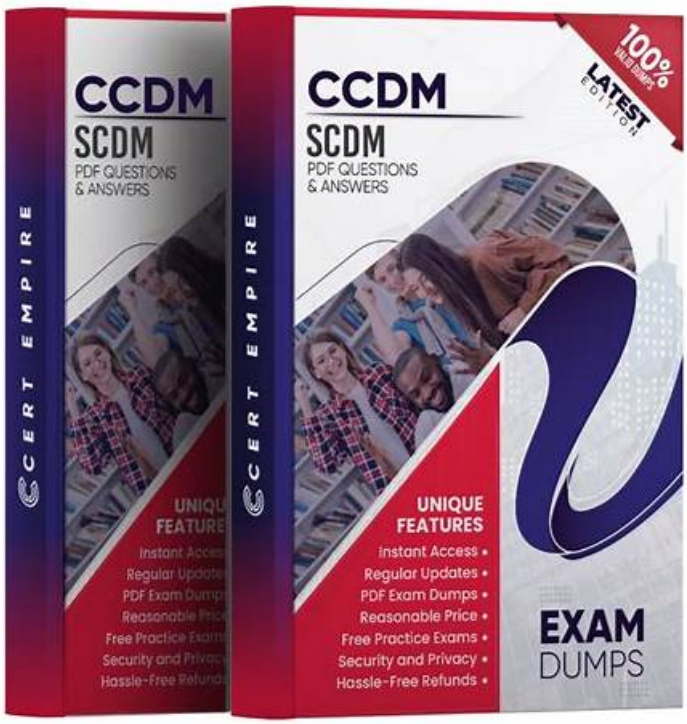

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SCDM Certified Clinical Data Manager Sample Questions (Q27-Q32):

NEW QUESTION # 27
A protocol amendment adds three data elements to the vital signs screen and two additional data-collection time points. Which is best practice for handling changes to the form completion guidelines?

- A. Notify sites of the change without a guideline update
- B. Update the guidelines and post the new version on the trial portal

- C. Rely on the revised CRF to enforce the changes without updating guidelines or notifying sites
- D. Update the guidelines and notify sites of changes prior to implementing the change

Answer: D

Explanation:
The best practice when implementing a protocol amendment that affects CRF content or data collection timing is to update the eCRF completion guidelines and notify sites before implementing the change.
According to the GCDMP (Chapter: CRF Design and Data Collection), the eCRF Completion Guidelines (eCRF CG) are an essential study tool that instructs site personnel on accurate and consistent data entry. When new data elements or collection time points are added, the guidelines must be revised, version-controlled, and communicated to all users prior to implementation to ensure sites collect and enter data correctly.
Simply relying on the revised CRF (option C) or updating the document without notification (option B) violates communication and training standards. Likewise, notifying sites without updating the documentation (option D) leaves insufficient reference material for data entry compliance.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.5 - Managing CRF Revisions and Site Communication ICH E6 (R2) GCP, Section 5.18.4 - Communication of Protocol Amendments and Documentation Updates FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, Section 4.3 - Site Communication and Documentation Management

NEW QUESTION # 28
Which is the MOST appropriate flow for EDC set-up and implementation?

- A. Database created, Database tested, Sites trained, Protocol finalized, Database released
- B. Database created, Subjects enrolled, Database tested, Sites trained, Database released
- C. CRF "wire-frames" created, CRFs reviewed, CRFs printed, CRFs distributed to sites
- D. Protocol finalized, Database created, Edit Checks created, Database tested, Sites trained

Answer: D

Explanation:
The correct and compliant sequence for EDC system setup and implementation begins only after the study protocol is finalized, as all case report form (CRF) designs, database structures, and validation rules derive directly from the finalized protocol.
According to GCDMP (Chapter: EDC Systems Implementation), the proper order is:
Protocol finalized - defines endpoints and data requirements.
Database created - built according to the protocol and CRFs.
Edit checks created - programmed to validate data entry accuracy.
Database tested (UAT) - ensures functionality, integrity, and compliance.
Sites trained and system released - only then can data entry begin.
Option B follows this logical and regulatory-compliant sequence. Other options (A, C, D) are either paper-based workflows or violate GCP-compliant timelines (e.g., enrolling subjects before database validation).
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - System Setup and Implementation Flow ICH E6(R2) GCP, Section 5.5.3 - Computerized Systems Validation and User Training Before Use FDA 21 CFR Part 11 - Validation and System Release Requirements

NEW QUESTION # 29
A study numbers subjects sequentially within each site and does not reuse site numbers. Which information is required when joining data across tables?

- A. Study number and subject number
- B. Subject number and site number
- C. Subject number
- D. Site number

Answer: B

Explanation:

When subjects are numbered sequentially within each site, it means that the subject identification numbers (Subject IDs) restart from 001 at each site. For example, Site 101 may have Subject 001, and Site 102 may also have a Subject 001. In such cases, the subject number alone is not globally unique across the entire study. Therefore, when integrating or joining data across multiple database tables (for example, linking demographic, adverse event, and laboratory data), both the site number and the subject number are required to create a unique key that accurately identifies each record.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection), every data record in a clinical trial database must be uniquely and unambiguously identified. This is typically achieved through a composite key, combining identifiers such as site number, subject number, and sometimes study number. The GCDMP specifies that a robust data structure must prevent duplication or mislinking of records across domains or tables.
Furthermore, FDA and CDISC standards (SDTM model) also emphasize the importance of unique subject identifiers (USUBJID), which are derived from concatenating the study ID, site ID, and subject ID. This ensures traceability, integrity, and accuracy of subject-level data during database joins, data exports, and regulatory submissions.
Thus, in the described scenario, since subject numbering restarts at each site, both the site number and subject number are required to uniquely identify and correctly join subject data across different datasets or tables.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 4.1 - Unique Subject Identification CDISC SDTM Implementation Guide, Section 5.2 - Subject and Site Identification (Variable: USUBJID) FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Integrity and Record Identification

NEW QUESTION # 30
When a data manager runs a report on resolution types of discrepancy status, which of the following would NOT be a part of resolution types?

- A. Cannot be resolved (but data incorrect)
- B. Data management - self evident corrections
- C. Resolved with data/confirmed as is (non problematic)
- D. Received from site and not yet reviewed

Answer: D

Explanation:
In a discrepancy management workflow, "Received from site and not yet reviewed" is not a resolution type - it represents a status, not a final resolution outcome.
According to the GCDMP (Chapter: Data Validation and Cleaning), resolution types describe how a data discrepancy was finalized or addressed, such as:
Resolved with data correction,
Confirmed as correct (no change required),
Self-evident correction applied by data management, or
Unresolvable discrepancies documented.
In contrast, statuses describe the stage of the query (e.g., open, sent, answered, pending review, closed). "Received from site and not yet reviewed" indicates an intermediate workflow state where the response awaits validation by data management.
Proper classification of resolution types is essential for performance reporting, audit readiness, and ensuring the traceability of query management actions under ICH E6 (R2) and FDA 21 CFR Part 11.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 5.3 - Discrepancy Resolution Lifecycle ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Data Handling and Record Management FDA 21 CFR Part 11 - Electronic Records; Audit Trails and Discrepancy Tracking Requirements

NEW QUESTION # 31
A Data Manager is designing a report to facilitate discussions with sites regarding late dat a. Which is the most important information to display on the report to encourage sites to provide data?

- A. Number of forms entered in the last week
- B. Total number of forms entered to date
- C. Expected versus actual forms entered
- D. List of outstanding forms

Answer: D

Explanation:
In managing site data timeliness, the most actionable and effective tool is a report listing all outstanding (missing or incomplete) CRFs.
According to GCDMP (Chapter: Communication and Study Reporting), Data Managers must provide site-level performance reports highlighting:
Outstanding CRFs not yet entered,
Unresolved queries, and
Pending data corrections.
Such reports help sites prioritize and address data gaps efficiently.
Option A and D are historical metrics without actionable context.
Option B gives a general overview but lacks specific site-level actionability.
Hence, option C (List of outstanding forms) provides the clearest and most motivating feedback to sites for timely data entry and query resolution.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Data Timeliness and Reporting Metrics ICH E6(R2) GCP, Section 5.1.1 - Sponsor Oversight and Data Communication Requirements FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Site-Level Data Timeliness Reporting

NEW QUESTION # 32
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