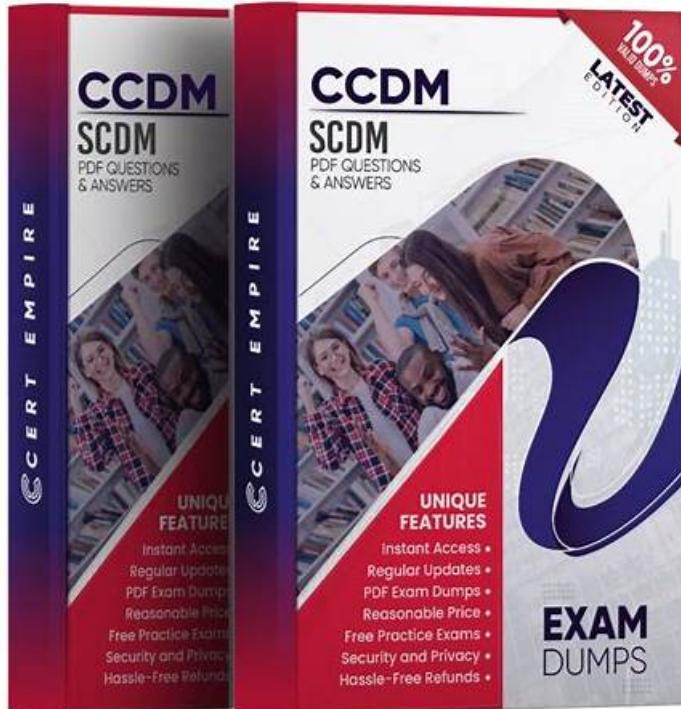


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SCDM Certified Clinical Data Manager Sample Questions (Q111-Q116):

NEW QUESTION # 111

Which is the best way to identify sites with high subject attrition?

- A. Number of late visits per site

- B. Number of patients for which two visit periods have passed without data
- C. Proportion of late visits by site
- D. Proportion of patients for which two visit periods have passed without data by site

Answer: D

Explanation:

The best method to identify sites with high subject attrition is to calculate the proportion of patients for which two visit periods have passed without data, by site.

According to the GCDMP (Chapter: Data Quality Assurance and Control), subject attrition is an important performance indicator for data completeness and site compliance. Evaluating missing or delayed data across multiple consecutive visit periods allows for early detection of potential dropouts or site-level operational issues.

By assessing this proportion at the site level, the Data Manager can distinguish between random missing data and systematic site underperformance. Counting or proportioning late visits (options B and C) identifies scheduling delays, not attrition. Looking at missing data without site context (option D) fails to identify site-specific patterns, limiting corrective action.

This metric aligns with risk-based monitoring (RBM) practices recommended by ICH E6 (R2) and FDA RBM Guidance, which promote proactive identification of sites at risk of data loss.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 5.4 - Site Performance Metrics ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Evaluation FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 6 - Site Performance Metrics

NEW QUESTION # 112

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

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

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 # 113

A study team member states that data entry can be done by clerical personnel at sites. Which are important considerations?

- A. Data entry at sites requires study-specific training on how to use the EDC system to enter data and respond to data discrepancies identified by the system
- B. The person at the sites who enters the data usually also understands which data in the medical record are needed for the study, where to find them and which value to choose
- C. It is possible that clerical personnel could be hired by sites because data entry requires little training and use of clerical personnel would reduce burden on sites
- D. Historically in clinical research site study coordinator roles have been filled by people with clinical or clinical research

experience

Answer: A

Explanation:

Although clerical staff can technically perform data entry, data entry in clinical research requires study-specific training, particularly in the use of the Electronic Data Capture (EDC) system and understanding data discrepancy resolution procedures.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection) and ICH E6 (R2), individuals responsible for data entry at clinical sites must be qualified by education, training, and experience. This includes understanding how to navigate the EDC system, enter data according to CRF Completion Guidelines, and appropriately respond to queries or system-generated edit checks.

Untrained clerical personnel may inadvertently introduce errors, violate Good Clinical Practice (GCP) standards, or fail to recognize protocol-relevant data. Therefore, the Data Manager must ensure that site users receive study-specific and system training before gaining access to the EDC environment.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.2 - Investigator Site Training and Data Entry Requirements ICH E6 (R2) Good Clinical Practice, Section 4.1.5 - Qualified Personnel and Training Requirements FDA 21 CFR Part 11 - User Access and Training Provisions for Electronic Records

NEW QUESTION # 114

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

Answer: D

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 # 115

In the transfer of obligations for a double-blind, multi-center trial, a sponsor has maintained the task of creating the randomization schedule. Who at the sponsor company should create the randomization schedule?

- A. The sponsor's project biostatistician
- B. The sponsor's project statistical programmer
- C. **A sponsor's biostatistician not on the project**
- D. The CRO biostatistician

Answer: C

Explanation:

In a double-blind clinical trial, the randomization schedule must be generated by an independent biostatistician not directly involved in study operations or data management to preserve study blinding and integrity.

According to ICH E9 and the GCDMP (Chapter: Regulatory Requirements and Compliance), randomization generation and blinding must be handled in a way that prevents bias or unintentional unblinding of study personnel. The sponsor's biostatistician not assigned to the project (Option C) is the appropriate person because they have the necessary statistical expertise but remain operationally independent from study execution.

A project biostatistician (Option D) or programmer (Option A) directly involved in data analysis could inadvertently compromise blinding. The CRO biostatistician (Option B) should not perform this function if the sponsor retains randomization responsibility. Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Regulatory Requirements and Compliance, Section 6.4 - Randomization and Blinding ICH E9 - Statistical Principles for Clinical Trials, Section 5.4 - Randomization Procedures and Blinding FDA Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics, Section 4.3 - Maintaining Blinding Integrity

NEW QUESTION # 116

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