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## SCDM CCDM

Certified Clinical Data Manager Exam

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Studying for attending Certified Clinical Data Manager exam pays attention to the method. The good method often can bring the result with half the effort, therefore we in the examination time, and also should know some test-taking skill. The CCDM quiz guide on the basis of summarizing the past years, found that many of the questions, the answers have certain rules can be found, either subjective or objective questions, we can find in the corresponding module of similar things in common. To this end, the Certified

Clinical Data Manager exam dumps have summarized some types of questions in the qualification examination, so that users will not be confused when they take part in the exam, to have no emphatic answers. It can be said that the template of these questions can be completely applied. The user only needs to write out the routine and step points of the CCDM test material, so that we can get good results in the exams.

## SCDM Certified Clinical Data Manager Sample Questions (Q85-Q90):

### NEW QUESTION # 85

During testing of an ePRO system, a test fails. Which information should be found in the validation documentation?

- A. Reconciliation datapoints
- B. Root cause analysis of the system errors
- C. Expected and actual results
- D. Training requirements

**Answer: C**

Explanation:

When a system validation test fails during Electronic Patient-Reported Outcome (ePRO) system testing, the validation documentation must record the expected results (what should have occurred) and the actual results (what occurred). According to the GCDMP (Chapter: Database Validation and Testing), proper system validation documentation ensures traceability, reproducibility, and compliance with FDA 21 CFR Part 11 and ICH E6 (R2). Each test case must include:

Test objective,  
Preconditions,  
Test steps,  
Expected results,  
Actual results, and  
Pass/fail status.

If a test fails, this documentation provides the objective evidence necessary for deviation handling, issue resolution, and re-testing. While a separate root cause analysis may be performed later (option D), the validation record itself must focus on verifying outcomes against predefined expectations.

Therefore, the correct answer is B - Expected and actual results.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Database Validation and Testing, Section 4.4 - Documentation of Test Results FDA 21 CFR Part 11 - Validation Requirements (Section 11.10(a)) ICH E6 (R2) GCP, Section 5.5.3 - Computer System Validation and Documentation

### NEW QUESTION # 86

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

**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):

**NEW QUESTION # 87**

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

- A. 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
- B. Historically in clinical research site study coordinator roles have been filled by people with clinical or clinical research experience
- C. 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
- D. 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

**Answer: C**

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 # 88**

Which is the MOST appropriate flow for EDC set-up and implementation?

- A. Database created, Database tested, Sites trained, Protocol finalized, Database released
- B. CRF "wire-frames" created, CRFs reviewed, CRFs printed, CRFs distributed to sites
- C. Database created, Subjects enrolled, Database tested, Sites trained, Database released
- 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 # 89

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

**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 # 90

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