

# 免費PDF SCDM CCDM考題寶典是行業領先材料&實用的CCDM: Certified Clinical Data Manager



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>> CCDM考題寶典 <<

## CCDM真題 - CCDM認證考試

雖然CCDM考古題學習資料非常受歡迎，但是我們還是為客戶提供了免費的SCDM CCDM試用DEMO，供考生體驗，我們也將不斷發布更多新版的題庫，以滿足IT行業日益增長的需求。我們將為您提供最新的SCDM CCDM題庫資料來準備考試，所有的題庫都可以在這裡獲得，使通過CCDM考試變得更加容易。Testpdf將是您獲得認證的最好選擇，我們保證您100%可以通過CCDM認證考試。

## 最新的 Clinical Data Management CCDM 免費考試真題 (Q127-Q132):

### 問題 #127

In development of CRF Completion Guidelines (CCGs), which is a minimum requirement?

- A. CCGs are designed from the perspective of the Study Biostatistician to ensure that the data collected can be analyzed
- **B. CCGs must include a version control on the updated document**
- C. CCGs are developed with representatives of Data Management, Biostatistics, and Marketing departments
- D. CCGs must be signed before database closure to include all possible protocol changes affecting CRF completion

答案: B

解題說明:

Case Report Form Completion Guidelines (CCGs) are essential study documents that instruct site staff on how to complete each field of the CRF correctly. A minimum requirement for CCGs, according to Good Clinical Data Management Practices (GCDMP, Chapter: CRF Design and Data Collection), is that they must include version control.

Option A describes an important design consideration but not a minimum compliance requirement. Option B is inaccurate, as CCGs

must be approved and implemented before data collection begins, not after. Option D includes an irrelevant stakeholder (Marketing).

Therefore, option C-"CCGs must include a version control on the updated document"-is correct and compliant with CCDM and GCP standards.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: CRF Design and Data Collection, Section 4.3 - Development and Maintenance of CRF Completion Guidelines ICH E6(R2) GCP, Section 8.2.1 - Essential Documents and Version Control Requirements

### 問題 #128

Which of the following data verification checks would most likely be included in a manual or visual data review step?

- A. Checking a value against a reference range
- B. Checking mandatory fields for missing values
- C. Checking an entered value against a valid list of values
- **D. Checking adverse event treatments against concomitant medications**

答案： D

解題說明：

Manual or visual data review is used to identify complex clinical relationships and contextual inconsistencies that cannot be detected by automated edit checks.

According to the GCDMP (Chapter: Data Validation and Cleaning), automated edit checks are ideal for structured validations, such as missing fields (option C), reference ranges (option D), or predefined value lists (option A). However, certain clinical cross-checks-such as verifying adverse event treatments against concomitant medication records-require clinical judgment and contextual understanding.

For example, if an adverse event of "severe headache" was reported but no analgesic appears in the concomitant medication log, the data may warrant manual review and query generation. These context-based checks are best performed by trained data reviewers or medical data managers during manual data review cycles.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.3 - Manual Review and Clinical Data Consistency Checks ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Clinical Data Review Responsibilities FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Data Verification Principles

### 問題 #129

In a cross-functional team meeting, a monitor mentions performing source data verification (SDV) on daily diary data entered by patients on mobile devices. Which of the following is the best response?

- A. The diary data should not be source data verified
- **B. Diary data to be source data verified should be selected using a risk-based approach**
- C. All diary data should be source data verified
- D. Diary data to be source data verified should be randomly selected

答案： B

解題說明：

The best response is that diary data to be source data verified should be selected using a risk-based approach.

According to the GCDMP (Chapter: Data Quality Assurance and Control) and FDA Guidance on Risk-Based Monitoring (RBM), not all data require full SDV. Electronic patient-reported outcome (ePRO) or mobile diary data are typically direct electronic source data (eSource) captured at the time of entry, which already ensures authenticity and traceability.

A risk-based SDV approach focuses verification efforts on data critical to subject safety and primary efficacy endpoints, as defined in the study's Risk Assessment Plan or Monitoring Plan. Random or full verification of low-risk data (like diary compliance metrics) adds unnecessary effort and cost.

Thus, Option C aligns with current regulatory expectations and data management best practices.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 7.3 - Risk-Based Monitoring and SDV ICH E6 (R2) Good Clinical Practice, Section 5.18 - Risk-Based Quality Management FDA Guidance for Industry: Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring (2013)

### 問題 #130

Which information should be communicated by the Data Manager at regular intervals throughout a study?

- A. Serious and unexpected safety events
- **B. Percent data entered and clean**
- C. Planned versus actual enrollment
- D. Site staffing changes

答案： B

解題說明：

The Data Manager (DM) plays a critical role in maintaining transparent communication with the clinical study team regarding data quality and study progress. One of the most essential metrics regularly reported by the DM is the percentage of data entered and cleaned.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Communication and Study Reporting), these metrics provide insight into study status, data readiness for interim analysis, and timeline predictability for database lock. Regular communication includes:

Percent of CRFs entered and verified

Percent of queries resolved

Outstanding data issues or missing pages

Other options fall outside the Data Manager's direct responsibility:

A (Enrollment) is typically reported by clinical operations.

B (Staffing changes) are handled by site management.

D (Safety events) are communicated by the safety/pharmacovigilance team.

Thus, option C correctly reflects the Data Manager's responsibility for ongoing study communication.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Communication and Study Reporting, Section 5.3 - Study Metrics and Status Updates ICH E6(R2)

GCP, Section 5.1.1 - Communication and Oversight in Quality Management FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.5 - Data Status Reporting

### 問題 #131

In an EDC study, user training and access must be monitored and addressed when all the following situations occur EXCEPT:

- A. Study team members are reassigned to a different role within the study.
- B. Site staff is new to the study.
- **C. A software upgrade is made that does not impact site staff or study team members.**
- D. Site staff moves off of the study.

答案： C

解題說明：

In Electronic Data Capture (EDC) studies, proper user training and access management are essential for maintaining data integrity, security, and regulatory compliance. According to the Good Clinical Data Management Practices (GCDMP) and FDA 21 CFR Part 11, EDC systems must ensure that only qualified and trained personnel can access study data, and that all access rights reflect current study responsibilities.

User training and access must therefore be reviewed and updated whenever:

Site staff leave the study (access revocation is required),

New site staff are added (training and credentialing are required), and Study team members change roles (access levels must be modified accordingly).

However, if a software upgrade occurs that does not impact the functional roles, user permissions, or data handling processes, retraining or reauthorization is not required. This is because such updates do not alter compliance-critical workflows or user interactions.

Therefore, the exception is C - when a software upgrade does not affect users.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.1 - User Access and Training Controls FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures, Section 11.10(i) & (k) ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - System Security and User Training

### 問題 #132

