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## Quiz 2026 SCDM Accurate CCDM: Certified Clinical Data Manager Valid Test Materials

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### SCDM Certified Clinical Data Manager Sample Questions (Q29-Q34):

#### NEW QUESTION # 29

An international study collects lab values. Sites use different units in the source documents. Which of the following data collection strategies will have fewer transcription errors?

- A. Have all sites convert the values to the same unit system on the data collection form
- B. Allow values to be entered as they are in the source and the selection of units on the data collection form
- C. Allow values to be entered as they are in the source document and derive the units based on the magnitude of the value
- D. Use a structured field and print standard units on the data collection form

**Answer: B**

Explanation:

In international or multicenter clinical studies, laboratory data often originate from different laboratories that use varying measurement units (e.g., mg/dL vs. mmol/L). The Good Clinical Data Management Practices (GCDMP, Chapter on CRF Design and Data Collection) provides clear guidance on managing this variability to ensure data consistency, traceability, and minimized transcription errors.

The approach that results in fewer transcription errors is to allow sites to enter lab values exactly as recorded in the source document (original lab report) and to require explicit selection of the corresponding unit from a predefined list on the data collection form or within the electronic data capture (EDC) system. This method (Option B) preserves the original source data integrity while enabling centralized or automated unit conversion later during data cleaning or statistical processing.

Option B also supports compliance with ICH E6 (R2) Good Clinical Practice (GCP), which mandates that transcribed data must remain consistent with the source documents. Attempting to derive units automatically (Option A) can lead to logical errors, while forcing sites to manually convert units (Option D) introduces unnecessary complexity and increases the risk of miscalculation or inconsistent conversions. Printing only standard units on the CRF (Option C) ignores local lab practices and can lead to discrepancies between CRF entries and source records, triggering numerous data queries.

The GCDMP emphasizes that CRF design must account for local variations in measurement systems and ensure that unit selection is structured (dropdowns, controlled lists) rather than free-text to prevent typographical errors and facilitate standardization during data transformation.

Therefore, Option B-"Allow values to be entered as they are in the source and the selection of units on the data collection form"-is the most compliant, accurate, and efficient strategy for minimizing transcription errors in international lab data collection.

Reference (CCDM-Verified Sources):

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: CRF Design and Data Collection, Section 5.4 - Laboratory Data Management and Unit Handling ICH E6 (R2) Good Clinical Practice, Section 5.18 - Data Handling and Record Retention CDISC SDTM Implementation Guide, Section 6.3 - Handling of Laboratory Data and Standardized Units FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data and Accuracy of Data Entry

### NEW QUESTION # 30

An organization conducts over fifty studies per year. Currently each study is specified and set-up from scratch. Which of the following organizational infrastructure options would streamline database set-up and study-to-study consistency?

- A. Improving the form or screen design process
- B. Implementing controlled terminology for adverse events
- C. Maintaining a library of form or screen modules
- D. Adopting an ODM compliant database system

**Answer: C**

Explanation:

To improve efficiency and ensure consistency across multiple studies, the most effective infrastructure solution is to maintain a centralized library of standardized forms or screen modules (e.g., CRF/eCRF templates).

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Database Design and Build), using a form library allows reuse of validated data collection modules for commonly collected domains such as demographics, adverse events, and vital signs. This reduces database setup time, enhances uniformity in data definitions, and ensures alignment with standards such as CDISC CDASH and SDTM.

While adopting ODM (A) provides standardized data exchange and interoperability, it does not inherently reduce setup workload. Improving design processes (C) enhances efficiency but doesn't guarantee consistency, and implementing controlled terminology (D) helps with coding standardization, not database structure.

Therefore, option B - maintaining a library of form or screen modules - provides the most direct and sustainable improvement for scalability and quality.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 5.3 - Use of Standard Libraries and Templates CDISC CDASH Implementation Guide, Section 3.2 - Reusable CRF Modules and Standardization ICH E6(R2) GCP, Section 5.5.3 - Standardization and Reuse in Data Collection Systems

### NEW QUESTION # 31

Which metric reveals the timeliness of the site-work dimension of site performance?

- A. Median and range of time from query generation to resolution
- B. Time from final protocol to first patient enrolled
- C. Time from site contract execution to first patient enrolled
- D. Time from Last Patient Last Visit to database lock

**Answer: A**

Explanation:

The site-work dimension of site performance evaluates how efficiently sites manage and resolve data-related tasks - particularly query resolution, data entry, and correction timelines. Among the given metrics, the median and range of time from query generation to resolution (D) directly measures the site's responsiveness and data management efficiency.

According to the GCDMP (Chapter on Metrics and Performance Measurement), this indicator helps identify sites that delay query resolution, which can impact overall study timelines and data quality. Tracking this metric allows the data management team to proactively provide additional training or communication to underperforming sites.

Other options measure different aspects of project progress:

A reflects overall database closure speed.

B and C relate to study startup and enrollment readiness, not ongoing data work.

Thus, option D accurately represents a site performance timeliness metric, aligning with CCDM principles for operational performance measurement.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Metrics and Performance Management, Section 5.4 - Site Query Resolution Metrics ICH E6(R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Performance Oversight

### NEW QUESTION # 32

A protocol is updated mid-study to add an additional procedure about which data needs to be collected. Which of these statements applies?

- A. The DMP does not need to be updated as it represents the data at the beginning of the trial only
- B. The DMP should be updated to reflect the changes to the protocol, but this update does not need to be communicated
- **C. The DMP should be updated to reflect the changes to the protocol and stakeholders notified**
- D. The DMP does not need to be updated until the end of the trial and all updates are included in the DMP to indicate what happened in the trial

**Answer: C**

Explanation:

When a protocol is amended mid-study, resulting in additional data collection requirements, the Data Management Plan (DMP) must be updated accordingly and all relevant stakeholders must be notified.

According to the GCDMP (Chapter: Data Management Planning and Study Start-up), the DMP is a living document that defines all data management processes for a clinical study. It must accurately reflect the current data flow, CRF design, validation procedures, and reporting structure. Any protocol amendments affecting data capture, structure, or analysis require immediate DMP revision and distribution to ensure alignment across data management, clinical, and biostatistics teams.

Failure to update and communicate DMP changes can lead to misalignment in data handling and introduce compliance risks during audits or inspections. Therefore, Option B is correct: the DMP must be updated and the change communicated to all stakeholders (e.g., sponsor, CRO, clinical operations, biostatistics).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Management Plan (DMP), Section 5.3 - Maintaining and Updating the DMP ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Documentation of Protocol Changes and Data Handling Procedures FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations - Section on Data Management Documentation

### NEW QUESTION # 33

The best example of a protocol compliance edit check is:

- **A. An edit check that fires when a visit date is outside the specified window**
- B. An edit check that fires when a field is left blank
- C. An edit check that fires when an invalid date is entered
- D. An edit check that fires when a value is outside of the normal range for vital signs

**Answer: A**

Explanation:

A protocol compliance edit check is designed to ensure that the data collected adheres to the specific requirements defined in the study protocol, such as visit timing, procedure windows, and eligibility criteria.

The example in option A - an edit check that triggers when a visit date falls outside the protocol-specified window - directly verifies compliance with the study design. This type of check supports real-time monitoring of protocol adherence, a critical quality and

regulatory requirement under GCDMP and ICH E6(R2).

Other options are examples of general data validation checks, not protocol compliance:

B: Ensures clinical plausibility (data range check).

C: Ensures completeness (missing data check).

D: Ensures format correctness (system validation check).

Thus, option A best represents a protocol compliance edit check, confirming that collected data conform to the visit schedule defined in the protocol.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Data Validation and Cleaning, Section 5.4 - Protocol Compliance Edit Checks ICH E6(R2) GCP, Section 5.1.1 - Quality Management and Compliance Controls FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6.3 - Edit Check Design and Validation

## NEW QUESTION # 34

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