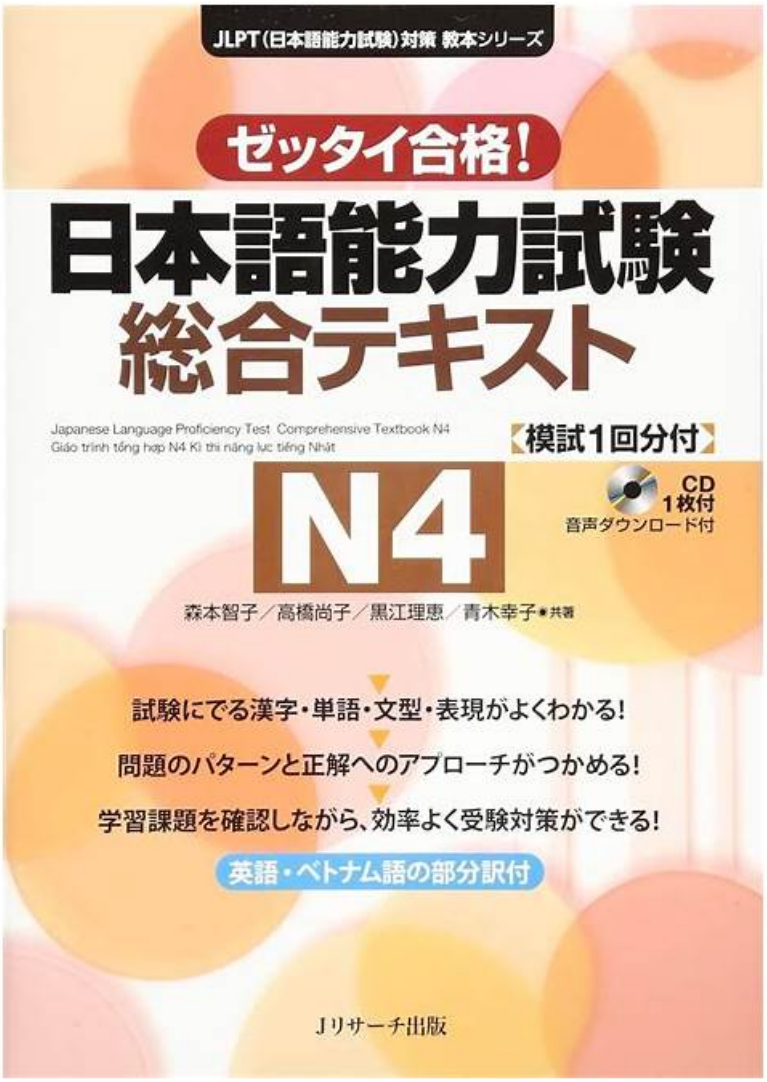
試験の準備方法-ユニークなCCDM日本語参考試験-完璧なCCDM認証pdf資料



P.S. MogiExamがGoogle Driveで共有している無料かつ新しいCCDMダンプ：https://drive.google.com/open?id=1ygachaLHR-KB4WOmCeEJAN8hOoDcI0vh

MogiExamは他の同様のプラットフォームとは異なり、CCDM実際のテストはSCDM購入前に無料で試用できるため、サンプルの質問とソフトウェアの使用方法を理解できます。 また、自分のニーズに基づいて決定を下すことができ、後悔することはありません。 そして、CCDM準備資料を改訂するために、専門家のグループを編成しました。 CCDMガイド急流のシンプルで理解しやすい言語は、学生であれオフィスワーカーであれ、学習者が困難を学ぶことから解放します。 そして、CCDMのCertified Clinical Data Manager試験問題の合格率は99％～100％です。

SCDM CCDM 認定試験の出題範囲：

トピック	出題範囲
トピック 1	• 調整とプロジェクト管理タスク: このドメインでは、データ管理ワークロード、ベンダーの選択、スケジュール、チーム間のコミュニケーション、プロジェクト タイムライン管理、リスク処理、メトリックの追跡、監査の準備の調整における臨床システム アナリストのスキルを評価します。

トピック 2	• テストタスク: このセクションでは、データ マネージャーのスキルを測定します。テスト計画の作成、テスト データの生成、検証およびユーザー受け入れテストの実行、およびシステムとプロセスが確実に仕様どおりに実行されるようにするための結果の文書化が含まれます。
トピック 3	• 設計タスク: CCDM 試験のこのセクションでは、データ マネージャーのスキルを測定し、データ収集機器の設計と文書化、ワークフローとデータ フローの開発、データ要素、CRF フォーム、編集チェック、レポート、データベース構造の指定、追跡可能性と監査可能性の標準と手順の定義方法について学習します。
トピック 4	• データ処理タスク: このセクションでは、臨床システムアナリストのスキルを測定し、データライフサイクル全体にわたって品質、一貫性、適切な権限を維持しながら、研究データの処理、変換、統合、調整、コーディング、クエリ、更新、アーカイブ化に焦点を当てます。
トピック 5	• レビュータスク: このセクションでは、データ マネージャーのスキルを測定し、プロトコル、CRF、データ テーブル、リスト、図、臨床試験レポート (CSR) をレビューして、一貫性、正確性、およびデータ処理の定義と規制要件との整合性を確認します。

>> CCDM日本語参考 <<

CCDM認証pdf資料 & CCDM最新テスト

より効果的に試験に合格する方法がわからないなら、私は良いトレーニングサイトを選ぶというアドバイスを差し上げます。そうしたら半分の労力で二倍の効果を得ることができますから。MogiExamはいつまでも受験生の皆さんにSCDMのCCDM認証試験の真実な試験トレーニング資料を提供することに力を尽くしています。MogiExamのSCDMのCCDM認証試験の問題集はソフトウェアベンダーがオーソライズした製品で、カバー率が高くて、あなたの大量の時間とエネルギーを節約できます。

SCDM Certified Clinical Data Manager 認定 CCDM 試験問題 (Q143-Q148):

質問 # 143
Based on the project Gantt chart as of 01 Nov 2019, an interim analysis is scheduled to occur early Q2 of 2020. All of the following are valid for initially assessing the status of data cleanliness EXCEPT:

- A. Identifying the number of discrepancies resolved to date
- B. Identifying missing pages where visits have been completed to date
- C. Identifying all outstanding discrepancies to date and aging
- D. Determining CRF data entry status of received pages

正解：A

解説：
When initially assessing data cleanliness in preparation for an interim analysis, the focus should be on outstanding issues that could affect data completeness and reliability.
According to the GCDMP (Chapter: Data Quality Assurance and Control), key indicators of readiness include:
The CRF data entry status of received pages (option A) to confirm completeness.
Identification of missing pages or visits (option B) to verify subject-level completeness.
A listing of outstanding discrepancies and their aging (option D) to assess unresolved data issues.
Counting the number of discrepancies resolved to date (option C), however, does not reflect data quality or current data readiness-it indicates past actions rather than current unresolved risks. Therefore, it is not a valid measure for assessing interim data cleanliness.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Data Quality Assurance and Control, Section 6.1 - Data Readiness Assessments for Analysis ICH E6 (R2) GCP, Section 5.18.4 - Ongoing Data Quality Review FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section 7 - Data Quality Indicators

質問 # 144
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. Site number
- C. Subject number and site number
- D. Subject number

正解：C

解説：
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

質問 # 145
Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Front-end check
- B. Programmed check
- C. Manual Check
- D. Back-end check

正解：A

解説：
A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.
Examples of front-end checks include:
Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).
Validating that a date is within an allowable range (e.g., not before the subject's date of birth).
Requiring mandatory fields to be completed before moving forward.
This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).
Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and

efficiency in data management operations.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

質問 # 146
Which of the following laboratory findings is a valid adverse event reported term that facilitates auto coding?

- A. Increased alkaline phosphatase, increased SGPT, increased SGOT, and elevated LDH
- B. ALT
- C. Elevated HDL
- D. Abnormal SGOT

正解：C

解説：
When coding adverse events (AEs) using MedDRA (Medical Dictionary for Regulatory Activities), valid AE terms must correspond to specific, medically meaningful concepts that match directly to a Preferred Term (PT) or Lowest Level Term (LLT) in the dictionary.
Among the options, "Elevated HDL" (High-Density Lipoprotein) represents a single, medically interpretable, and standard term that can directly match to a MedDRA LLT or PT. This makes it suitable for auto-coding, where the system automatically maps verbatim terms to MedDRA entries without manual intervention.
In contrast:
ALT (B) and Abnormal SGOT (C) are incomplete or nonspecific; they describe test names or qualitative interpretations rather than events.
Option D lists multiple findings, making it too complex for automatic mapping. Such compound entries would require manual coding review.
According to GCDMP (Chapter: Medical Coding and Dictionaries), a valid AE term should be:
Clinically interpretable (not just a lab test name)
Unambiguous
Single-concept based, not a collection of results
Thus, option A (Elevated HDL) is correct, as it aligns with MedDRA's single-concept, standard terminology structure suitable for auto-coding.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Medical Coding and Dictionaries, Section 5.3 - Auto-coding and Verbatim Term Management ICH M1 MedDRA Term Selection: Points to Consider, Section 2.1 - Coding Principles ICH E2B(R3) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports

質問 # 147
A Data Manager is designing a CRF for a study for which the efficacy data are not covered by the current SDTM domains. Which of the following should the Data Manager consult first?

- A. A CDISC therapeutic-area implementation guide
- B. Forms used by other sponsors in the same therapeutic area
- C. SNOMED terms used in the therapeutic area
- D. Data elements used in clinical registries in the therapeutic area

正解：A

解説：
When efficacy data are not covered by existing CDISC SDTM domains, the first resource the Data Manager should consult is the CDISC Therapeutic Area Implementation Guide (TAIG) for that therapeutic field.
According to the GCDMP (Chapter: Standards and Data Mapping), CDISC's Therapeutic Area User Guides (TAUGs) and Implementation Guides provide standardized data structures, variable definitions, controlled terminology, and implementation examples for specific diseases or therapeutic areas. These guides ensure consistency across studies, promote interoperability, and align data collection with regulatory submission expectations.
Consulting other sponsors' forms or external registries (options A and C) can be informative but do not provide authoritative

CDISC-compliant standards. SNOMED terms (option B) address medical terminology, not structural data domain definitions. Therefore, Option D is correct-CDISC TA Implementation Guides are the recognized primary reference when extending or designing SDTM-compliant CRFs.
Reference (CCDM-Verified Sources):
SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Standards and Data Mapping, Section 4.2 - Use of CDISC Standards CDISC Therapeutic Area User Guides (TAUGs) - Implementation Guidance for Domain Extension FDA Data Standards Catalog - CDISC Therapeutic Area Standards

質問 # 148
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CCDM認証pdf資料: https://www.mogiexam.com/CCDM-exam.html

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