

CCDM적중율높은시험덤프최신버전시험대비자료



BONUS!!! PassTIP CCDM 시험 문제집 전체 버전을 무료로 다운로드하세요: <https://drive.google.com/open?id=1JNbcZGfIB4yLnlyGYUJ78Xj6HoToIdrg>

PassTIP는 아주 우수한 IT인증자료사이트입니다. 우리PassTIP에서 여러분은SCDM CCDM인증시험관련 스킬과 시험자료를 얻을수 있습니다. 여러분은 우리PassTIP 사이트에서 제공하는SCDM CCDM관련자료의 일부분문제와답 등 샘플을 무료로 다운받아 체험해볼 수 있습니다. 그리고PassTIP에서는SCDM CCDM자료구매 후 추후 업데이트 되는 동시에 최신버전을 무료로 발송해드립니다. 우리는SCDM CCDM인증시험관련 모든 자료를 여러분들에서 제공할 것입니다. 우리의 IT전문 팀은 부단한 업계경험과 연구를 이용하여 정확하고 디테일 한 시험문제와 답으로 여러분을 어시스트 해드리겠습니다.

SCDM CCDM인증시험패스에는 많은 방법이 있습니다. 먼저 많은 시간을 투자하고 신경을 써서 전문적으로 관련 지식을 터득한다거나; 아니면 적은 시간투자과 적은 돈을 들여 PassTIP의 인증시험덤프를 구매하는 방법 등이 있습니다.

>> CCDM적중을 높은 시험덤프 <<

CCDM최신버전 덤프자료 & CCDM시험대비 덤프공부문제

PassTIP는 유일하게 여러분이 원하는SCDM인증CCDM시험관련자료를 해결해드릴 수 있는 사이트입니다. PassTIP에서 제공하는 자료로 응시는 문제없습니다. 여러분은 고득점으로 시험을 통과할 것입니다.

최신 Clinical Data Management CCDM 무료샘플문제 (Q33-Q38):

질문 # 33

Before the EDC system used for the trial is upgraded, what should be the data manager's first task?

- A. Assess the impact on the data
- B. Update the user manual
- C. Redesign the eCRF
- D. Notify the sites of the upgrade

정답: A

설명:

Before implementing an EDC system upgrade, the first task of the Data Manager is to assess the impact on the data.

According to the GCDMP (Chapter: Electronic Data Capture Systems) and FDA 21 CFR Part 11, any system upgrade must undergo impact assessment to determine how the change might affect data integrity, functionality, validation, and ongoing study operations. This assessment ensures that no data are lost, corrupted, or rendered inconsistent during or after the upgrade.

The Data Manager should evaluate:

Potential effects on existing data, edit checks, and reports,

System functionality impacting current workflows, and

Any revalidation requirements.

Only after the impact is understood should the Data Manager proceed to communicate with sites (option A), update documentation (option B), or modify CRFs if required (option D).

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Electronic Data Capture Systems, Section 7.3 - System Upgrades and Change Control FDA 21 CFR Part 11 - Change Control and Validation Requirements ICH E6 (R2) Good Clinical Practice, Section 5.5.3 - Change Impact on Data Integrity and System Validation

질문 # 34

An organization has completed a study and wants to submit the data to the FDA using CDISC SDTM. Which of the following must be done?

- A. SDTM cannot be used in this situation
- B. Provide a letter of intent to use SDTM to the FDA
- C. Map and transform the study data to SDTM
- D. Re-enter the data into an SDTM compliant system

정답: C

설명:

To submit study data to the FDA in CDISC SDTM format, the sponsor must map and transform the collected data from the study's operational database (e.g., EDC) into SDTM-compliant domains.

According to GCDMP (Chapter: Standards and Data Integration) and CDISC SDTM Implementation Guide, this process includes:

Mapping raw data elements from the clinical database to SDTM domains (e.g., DM, AE, VS).

Transforming data to comply with SDTM structural and naming conventions.

Validating the output using CDISC compliance tools (e.g., Pinnacle 21).

Re-entering data (B) is unnecessary, and a letter of intent (C) is not required. SDTM is explicitly accepted by FDA for both retrospective and prospective submissions, so (D) is incorrect.

Thus, option A is correct - map and transform existing data to SDTM format for regulatory submission.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Standards and Data Integration, Section 5.3 - Data Transformation and CDISC Mapping CDISC SDTM Implementation Guide, Version 3.4 - Data Conversion and Submission Requirements FDA Study Data Technical Conformance Guide, Section 2.2 - SDTM Mapping and Validation

질문 # 35

A Data Manager is drafting a report for clinical operations staff for support in responding to questions about milestone-based site payments. Which is the most important information to display?

- A. Milestones met by month, by type

- B. Expected versus actual milestones met to date, by site
- C. Milestones met by month, by site
- D. Milestones included in the last payment by site, by patient

정답: B

설명:

When reporting milestone-based site payment information, the most critical information to include is expected versus actual milestones met to date, by site.

According to the Good Clinical Data Management Practices (GCDMP, Chapter: Project Management and Communication), effective reporting must support operational and financial decision-making by presenting performance indicators in a clear, actionable format. Site payments in clinical studies are typically tied to specific milestones such as subject enrollment, visit completion, or data cleaning achievements.

By comparing expected (planned) versus actual (achieved) milestones per site, the Data Manager provides clinical operations staff with an accurate view of site progress and payment eligibility. This allows for identification of delayed sites, forecasting of upcoming payments, and early intervention for underperforming centers.

While milestone summaries by month or type (options A and B) may be useful for trend analysis, they lack the operational detail required for financial tracking. Milestone data by patient (option D) is overly granular for site-level payment management.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Project Management and Communication, Section 6.2 - Data Reporting for Site Performance and Payments ICH E6 (R2) Good Clinical Practice, Section 5.18.4 - Communication and Monitoring Reports FDA Guidance for Industry: Oversight of Clinical Investigations - Site Management and Reporting

질문 # 36

What should be done if the site continues to provide inconsistent data after several re-queries?

- A. Escalate the issue to the appropriate site contact personnel
- B. Gently lead the site to the correct response
- C. Continue to re-query until the site changes the data
- D. Do nothing, the data will remain inconsistent

정답: A

설명:

If a clinical site continues to provide inconsistent or illogical data after multiple queries, the correct course of action is to escalate the issue to the appropriate site contact personnel, typically the Clinical Research Associate (CRA) or Site Monitor.

According to the Good Clinical Data Management Practices (GCDMP), persistent data discrepancies often indicate a misunderstanding of the protocol, CRF instructions, or data entry procedures at the site level. Repeatedly re-querying the same data without escalation wastes time and risks introducing bias or error. By escalating through formal communication channels, the issue can be clarified through re-training, documentation review, or site monitoring visits.

The GCDMP emphasizes that escalation ensures data accuracy, site accountability, and protocol adherence, maintaining both data quality and regulatory compliance. Data managers must document the escalation process in the Data Management Plan (DMP) and ensure proper follow-up resolution is achieved.

Reference (CCDM-Verified Sources):

SCDM Good Clinical Data Management Practices (GCDMP), Chapter: Communication and Issue Escalation, Section 4.2 - Handling Persistent Data Discrepancies ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Site Communication FDA Guidance for Industry: Oversight of Clinical Investigations - Risk-Based Monitoring, Section on Issue Escalation

질문 # 37

Which database table structure is most appropriate for vital signs data collected at every-other visit for each patient in a study?

- A. One record per visit
- B. One record per patient
- C. One record per patient per visit
- D. One record per patient per study

정답: C

설명:

In a relational clinical database, the most efficient and normalized structure for data collected repeatedly over time-such as vital signs-is one record per patient per visit.

Each patient will have multiple records, one for each visit when vital signs are assessed. This structure supports:

Time-based analysis (e.g., trends across visits),

Accurate data linkage with visit-level metadata, and

Efficient querying for longitudinal data.

According to the GCDMP (Chapter: Database Design and Build), the relational design principle dictates that data should be stored at the lowest unique level of observation. Since vital signs vary by both patient and visit, the combination of patient ID + visit ID forms a unique key for each record.

Option A (per visit) lacks patient identification, while options B and D aggregate data too broadly, losing temporal detail.

Thus, option C (One record per patient per visit) correctly represents the normalized design structure.

Reference (CCDM-Verified Sources):

SCDM GCDMP, Chapter: Database Design and Build, Section 4.2 - Normalization and Table Structure CDISC SDTM

Implementation Guide, Section 5.3 - Visit-Level and Observation-Level Data Structures ICH E6(R2) GCP, Section 5.5.3 - Data Handling Principles

질문 # 38

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PassTIP의SCDM CCDM덤프는 레알시험의 모든 유형을 포함하고 있습니다.객관식은 물론 드래그앤드랍,시물문제 등 실제시험문제의 모든 유형을 포함하고 있습니다. SCDM CCDM덤프의 문제와 답은 모두 엘리트한 인증강사 및 전문가들에 의하여 만들어져SCDM CCDM 시험응시용만이 아닌 학습자료용으로도 손색이 없는 덤프입니다.저희 착한SCDM CCDM덤프 데려가세용~!

CCDM최신버전 덤프자료 : <https://www.pass4test.net/CCDM-pass-exam.html>

여러분이 다른 사이트에서도 관련덤프자료를 보셨을경우 페이지 아래를 보면 자료출처는 당연히 PassTIP CCDM 최신버전 덤프자료 일 것입니다, SCDM CCDM적중을 높은 시험덤프 저희 덤프로 쉬운 자격증 취득이 가능할것입니다, SCDM CCDM적중을 높은 시험덤프 하루빨리 덤프를 공부하여 자격증 부자가 되세요, 저희 SCDM CCDM덤프에 있는 문제와 답만 기억하시면 CCDM시험을 패스할수 있다고 굳게 믿고 있습니다, 다른 사람보다 빠르게 CCDM 인증시험을 패스하여 자격증을 취득하고 싶은 분은 PassTIP 에서 출시한 CCDM덤프로 시험준비를 하시면 됩니다, SCDM CCDM적중을 높은 시험덤프 만약 시험에서 떨어진다면 덤프전액환불을 약속 드립니다.

뭔가 이상한 것 같아 고개를 기울이자 웃고 있는 렌슈타인이 보였다, 사실이 아닙니다, CCDM여러분이 다른 사이트에서도 관련덤프자료를 보셨을경우 페이지 아래를 보면 자료출처는 당연히 PassTIP 일 것입니다, 저희 덤프로 쉬운 자격증 취득이 가능할것입니다.

CCDM 덤프 SCDM 자격증 덤프

하루빨리 덤프를 공부하여 자격증 부자가 되세요, 저희 SCDM CCDM덤프에 있는 문제와 답만 기억하시면 CCDM 시험을 패스할수 있다고 굳게 믿고 있습니다, 다른 사람보다 빠르게 CCDM 인증시험을 패스하여 자격증을 취득하고 싶은 분은 PassTIP 에서 출시한 CCDM덤프로 시험준비를 하시면 됩니다.

- CCDM최신버전 인기 덤프문제 □ CCDM인기자격증 최신시험 덤프자료 □ CCDM퍼펙트 공부문제 □ □ www.pass4test.net □에서 검색만 하면{ CCDM }를 무료로 다운로드할 수 있습니다CCDM유효한 최신덤프
- 시험준비에 가장 좋은 CCDM적중을 높은 시험덤프 덤프데모문제 보기 □ 지금 【 www.itdumpskr.com 】을 (를) 열고 무료 다운로드를 위해⇒ CCDM □를 검색하십시오CCDM시험패스 가능한 인증공부자료
- CCDM적중을 높은 시험덤프 최신 인기시험 덤프 데모문제 □□ 무료 다운로드를 위해 【 CCDM 】를 검색하려면 (kr.fast2test.com) 을(를) 입력하십시오CCDM인기자격증 최신시험 덤프자료
- CCDM 100% 시험패스 덤프자료 □ CCDM인기덤프 □ CCDM퍼펙트 공부문제 □ ⇒ www.itdumpskr.com □□□웹사이트를 열고 「 CCDM 」를 검색하여 무료 다운로드CCDM시험대비 공부하기
- CCDM적중을 높은 시험덤프 최신 인기시험 덤프 데모문제 □ ▶ www.dumptop.com ◀을(를) 열고 (CCDM)를 검색하여 시험 자료를 무료로 다운로드하십시오CCDM Vce
- CCDM적중을 높은 시험덤프 덤프문제 □ 무료 다운로드를 위해 지금 ⇒ www.itdumpskr.com □□□에서> CCDM ◀검색CCDM유효한 최신덤프
- CCDM적중을 높은 시험덤프 덤프문제 □ □ CCDM □를 무료로 다운로드하려면[www.pass4test.net]웹사이트를 입력하세요CCDM인기자격증 덤프공부자료
- CCDM적중을 높은 시험덤프 최신 인기시험 공부문제 □ 무료 다운로드를 위해✓ CCDM □✓□를 검색하려면□ www.itdumpskr.com □을(를) 입력하십시오CCDM 100% 시험패스 덤프자료
- 최신 CCDM적중을 높은 시험덤프 시험대비 공부문제 □ 오픈 웹 사이트> www.dumptop.com ◀검색⇒ CCDM

□ 무료 다운로드 CCDM 덤프 샘플 문제 체험

- CCDDM유료한 최신덤프 □ CCDDM유료한 최신덤프 ♥□ CCDDM최신버전 인기덤프 □ ⇒ www.itdumpskr.com ⇐ 웹사이트에서> CCDDM □를 열고 검색하여 무료 다운로드CCDDM 100% 시험패스 덤프자료
- CCDDM적중을 높은 시험덤프 최신 인기시험 공부문제 □ ➡ www.passtip.net □을(를) 열고✓ CCDDM □✓□ 를 입력하고 무료 다운로드를 받으십시오CCDDMin기덤프
- www.stes.tyc.edu.tw, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, w457084.s144.myverydz.cn, dietechnannie.co.za, protech.ecend.us, skillhivebd.com, www.stes.tyc.edu.tw, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, myportal.utt.edu.tt, Disposable vapes

PassTIP CCDM 최신 PDF 버전 시험 문제집을 무료로 Google Drive에서 다운로드하세요: <https://drive.google.com/open?id=1JNbcZGflB4yLnlyGYUJ78Xj6HoToIdrq>