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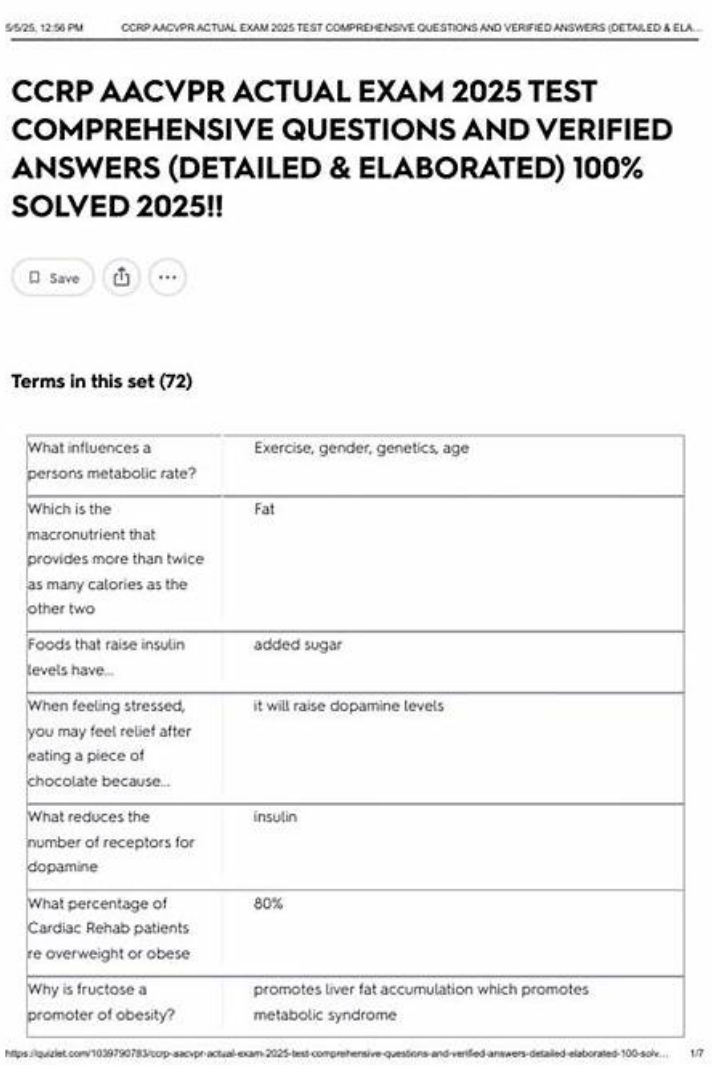

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CCRP AACVPR ACTUAL EXAM 2025 TEST COMPREHENSIVE QUESTIONS AND VERIFIED ANSWERS (DETAILED & ELABORATED) 100% SOLVED 2025!!

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Terms in this set (72)

What influences a persons metabolic rate?	Exercise, gender, genetics, age
Which is the macronutrient that provides more than twice as many calories as the other two	Fat
Foods that raise insulin levels have...	added sugar
When feeling stressed, you may feel relief after eating a piece of chocolate because...	it will raise dopamine levels
What reduces the number of receptors for dopamine	insulin
What percentage of Cardiac Rehab patients re overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.
Topic 2	• Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement.|Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q55-Q60):

NEW QUESTION # 55
In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties andfunctions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The CRO
- B. The sponsor
- C. The IRB/IEC
- D. The investigator

Answer: B

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."Hence, D is correct.
References:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).==========

NEW QUESTION # 56
During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

- A. Personnel records
- B. Standard Operating Procedures (SOPs)
- C. Financial reports
- D. Audit reports

Answer: D

Explanation:
Sponsor audits ensure systems comply with GCP.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include a review ofquality assurance audits and audit reports."
* Audit reports document findings from independent evaluations and are essential for ensuring compliance.
SOPs (A) are reviewed during audits but are not mandated as standalone "audit review documents." Personnel files (B) and financial reports (C) are not required under GCP auditing provisions.
Correct answer:D (Audit reports).
References:
ICH E6(R2), §5.19.3.

NEW QUESTION # 57
A physician with 20 years of experience is planning to be the site investigator for a multi-center, Phase I oncology clinical trial. In accordance with the ICH GCP Guideline, which of the following documents should the physician provide to the sponsor and the IRB/IEC?

- A. Proof of citizenship
- B. A copy of medical license
- C. A curriculum vitae
- D. A letter of recommendation from a fellow physician

Answer: C

Explanation:
Investigators must provideevidence of qualificationsto conduct the study.
* ICH E6(R2) 4.1.1:"The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial."
* ICH E6(R2) 8.2.10:Essential documents include thecurriculum vitae (CV)or other documents evidencing investigator qualifications, submitted to both sponsor and IRB/IEC.
Proof of citizenship (A) and letters of recommendation (B) are irrelevant. A copy of a medical license (D) may be provided but isnot specifically requiredby ICH. The CV is the universally required document.
Thus, the correct answer isC (Curriculum vitae).
References:
ICH E6(R2), §4.1.1 (Investigator qualifications).
ICH E6(R2), §8.2.10 (Essential documents: CV).

NEW QUESTION # 58
A subject was instructed to do a glucose check 4 times a day for 10 days using an investigational glucose meter. The meter requires one new glucose test strip for each test. The subject received the meter along with
45 glucose test strips. How many unused test strips should the subject have after the 10 days?

- A. 0
- B. 1
- C. 2
- D. 3

Answer: C

Explanation:
This is adrug/device accountability calculation question, testing compliance with investigational product tracking.
* The subject was instructed to perform4 glucose checks per day.
* Over10 days, that equals40 tests (4 × 10 = 40).
* Each test requires1 strip, so40 strips used.
* Subject was given45 strips, leaving5 unusedafter 10 days.
Investigators are responsible for maintaining accurate device/product accountability.
* ICH E6(R2) 4.6.3:"The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."
* This ensures monitoring can confirm that product/device use aligns with the protocol and subject adherence.
Thus, the correct answer isB (5 unused test strips).
References:

ICH E6(R2), §4.6.3 (Investigational product accountability).

NEW QUESTION # 59
Which countries have officially adopted ICH-GCP E6(R2) as a standard, in addition to U.S., EU, Japan, Canada, and Australia?

- A. China
- B. Switzerland
- C. India
- D. Brazil

Answer: C

Explanation:
India has aligned national regulations with ICH-GCP.
* DCGI/ICMR Guidelines (India):Explicitly adopt ICH E6(R2) as part of its Good Clinical Practice standards.China and Brazil are harmonizing, but full official adoption is noted in India.
References:Indian GCP Guidelines (2017 revision).

NEW QUESTION # 60
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