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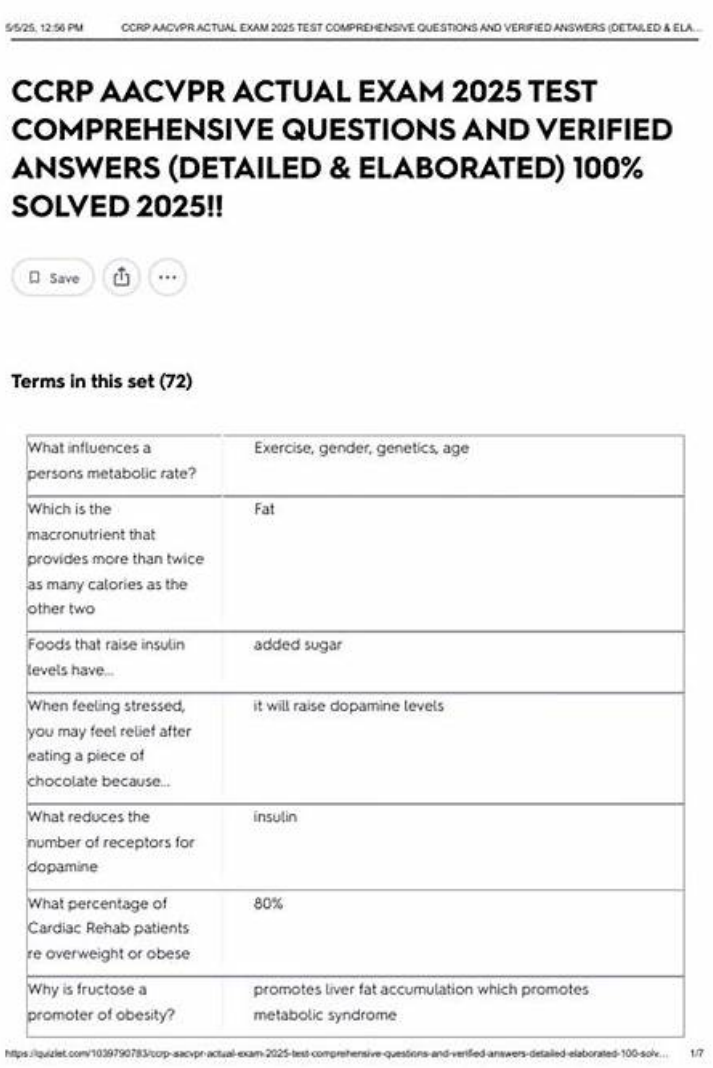

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Terms in this set (72)

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 (Q52-Q57):

NEW QUESTION # 52
A study will enroll 420 subjects over 3.5 years. What is expected average monthly accrual?

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

Answer: C

Explanation:
420 subjects ÷ 42 months (3.5 years) =10 subjects/month.
However, "expected average" often rounds up to next whole number, ensuring enrollment goals are met. Thus,
11/monthis correct.
This calculation is important for feasibility assessments and protocol planning.
References:Standard feasibility calculations (ICH E6(R2) §5.6).

NEW QUESTION # 53
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Dispensing instructions
- B. Lab draw requirements
- C. Results of recent nude mouse study
- D. Schedule of events

Answer: C

Explanation:
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:
ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 54
A research site was invited to participate in an investigational drug study. Which of the following parties is responsible for determining the risk-benefit ratio at the site?

- A. The site's legal counsel
- B. The clinical investigator
- C. The sponsor
- D. The IRB/IEC

Answer: D

Explanation:
Therisk-benefit ratiois a core responsibility of the IRB/IEC.
* 21 CFR 56.111(a)(2):"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."
* ICH E6(R2) 3.1.2:IRB/IEC must safeguard rights, safety, and well-being of subjects, with special attention to risk-benefit evaluation.
Investigators (A) provide medical judgment but do not formally approve the risk-benefit balance. Sponsors (D) design studies but must submit to IRB for independent review. Legal counsel (C) is not part of the scientific/ethical evaluation.
Thus,IRB/IEC is directly responsible for approving the risk-benefit ratio.
References:
21 CFR 56.111(a)(2).
ICH E6(R2), §3.1.2.

NEW QUESTION # 55
Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It is an application to export the investigational drug
- B. It includes a disclosure of the financial interests and arrangements of clinical investigators
- C. It includes the rationale for human testing and a description of the general investigational plan
- D. It is an application for the sponsor to sell the drug for profit

Answer: C

Explanation:
AnInvestigational New Drug (IND) applicationprovides FDA with data to justify human testing.
* 21 CFR 312.23(a)(3):The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."
* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.
Financial disclosures (D) are reported separately under21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.
Thus, the correct answer isB (Rationale and plan for human testing).
References:
21 CFR 312.23(a)(3) (IND contents).
21 CFR 312.20 (General IND requirements).

NEW QUESTION # 56
In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Maintaining case histories that record all observations and other data pertinent to the investigation
- B. Overseeing the administration of the investigational drug to the subjects
- C. Submitting progress reports to the reviewing IRB/IEC
- D. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug

Answer: D

Explanation:
Sponsors are responsible for distributing safety updates across all investigators and the FDA.
* 21 CFR 312.55(b):"The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:
* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).
* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).
* Administration of investigational drug (A) is managed by the investigator at site level.
Thus, the correct answer isB (Ensuring FDA and investigators are promptly informed).
References:
21 CFR 312.55(b) (Sponsor notification requirements).

NEW QUESTION # 57
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