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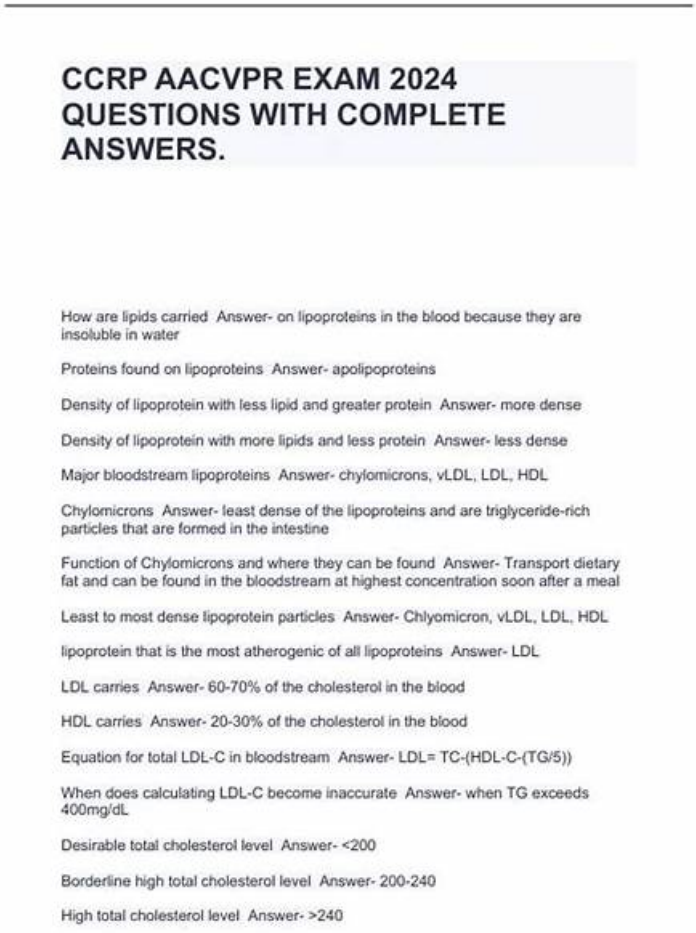
CCRP AACVPR EXAM 2024 QUESTIONS WITH COMPLETE ANSWERS.

How are lipids carried Answer- on lipoproteins in the blood because they are insoluble in water

Proteins found on lipoproteins Answer- apolipoproteins

Density of lipoprotein with less lipid and greater protein Answer- more dense

Density of lipoprotein with more lipids and less protein Answer- less dense

Major bloodstream lipoproteins Answer- chylomicrons, vLDL, LDL, HDL

Chylomicrons Answer- least dense of the lipoproteins and are triglyceride-rich particles that are formed in the intestine

Function of Chylomicrons and where they can be found Answer- Transport dietary fat and can be found in the bloodstream at highest concentration soon after a meal

Least to most dense lipoprotein particles Answer- Chlyomicron, vLDL, LDL, HDL

lipoprotein that is the most atherogenic of all lipoproteins Answer- LDL

LDL carries Answer- 60-70% of the cholesterol in the blood

HDL carries Answer- 20-30% of the cholesterol in the blood

Equation for total LDL-C in bloodstream Answer- LDL= TC-(HDL-C-(TG/5))

When does calculating LDL-C become inaccurate Answer- when TG exceeds 400mg/dL

Desirable total cholesterol level Answer- <200

Borderline high total cholesterol level Answer- 200-240

High total cholesterol level Answer- >240

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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 (Q49-Q54):

NEW QUESTION # 49
A physician wants to conduct research using an approved/marketed cardiac stent for use in the carotid artery, which is not an indication for which the device is approved. In this case, the physician must obtain which of the following?

- A. IRB/IEC and manufacturer approval
- B. The Office for Human Research Protections (OHRP) and manufacturer approvals
- C. IRB/IEC approval and an FDA IDE
- D. IRB/IEC approval and an FDA IND

Answer: C

Explanation:
When a physician investigates amedical device for a new use (off-label indication), FDA regulations classify this as aSignificant Risk Device Study, requiring anInvestigational Device Exemption (IDE)in addition to IRB approval.
* 21 CFR 812.20(a):"A sponsor shall submit an application to FDA for aninvestigational device exemption (IDE)if the device is to be used in a clinical investigation to determine safety and effectiveness."
* 21 CFR 812.2(b):Significant Risk device studies requireboth FDA and IRB approvalbefore initiation.
An IND (B) applies to drugs and biologics, not devices. Manufacturer permission (A, D) is not a regulatory requirement, although collaboration may be necessary. OHRP approval is not applicable.
Thus, the correct answer isC (IRB/IEC approval and an FDA IDE).
References:
21 CFR 812.20(a) (IDE submission requirements).
21 CFR 812.2(b) (Significant risk device studies).

NEW QUESTION # 50
In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Written information to be provided to the subjects
- B. Sponsor's SOPs
- C. IRB/IEC requirements for reporting to the regulatory authority
- D. Requirements for storage of the investigational product

Answer: C

Explanation:
Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.
* ICH E6(R2) 5.18.4:Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.
* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B).
However,IRB/IEC requirements for reporting to regulatory authoritiesare outside a monitor's scope.
That responsibility lies with investigators and IRBs under21 CFR 56.108(b).
Thus, the correct answer isD.
References:
ICH E6(R2), §5.18.4.
21 CFR 56.108(b).

NEW QUESTION # 51
Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- A. Death due to disease progression, mentioned in the investigator's brochure
- B. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug
- C. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure
- D. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy

Answer: B

Explanation:
Sponsors must reportserious, unexpected, and suspected adverse reactions (SUSARs)to the FDA.
* 21 CFR 312.32(c)(2):"Any adverse experience associated with the use of the drug that is bothserious and unexpectedshall be reported...as soon as possible but no later than 7 calendar daysafter the sponsor's initial receipt of the information, if it is fatal or life-threatening."
* ICH E2A 4.2:Requires expedited reporting oflife-threatening or fatal SUSARswithin 7 days.
Among the options, only (C) -death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related- meets the definition of a SUSAR requiring7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.
Thus, the correct answer isC.
References:
21 CFR 312.32(c)(2) (Expedited safety reporting).
ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

NEW QUESTION # 52
Upon completion of a study, the investigator should do which of the following?

- A. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- B. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- C. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome
- D. Ensure that all payments from sponsor have been received

Answer: C

Explanation:

Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 53
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Obtain IRB/IEC approval for revised protocol and ICF
- B. Execute material transfer agreement
- C. Notify enrolled subjects
- D. Ship under dangerous goods requirements

Answer: A

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 54
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