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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 are overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q16-Q21):

NEW QUESTION # 16

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

Answer: A

Explanation:

Sponsor audits ensure systems comply with GCP.

* ICH E6(R2) 5.19.3: "The sponsor's auditing procedures should include a review of quality 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 # 17

Why would a Phase IV study be conducted?

- A. Different off-label population
- B. Different schedule of administration
- C. Different marketing strategy
- D. Different dosage

Answer: A

Explanation:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

* ICH E8(R1): Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

* They often test drugs in new or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses on new patient populations or long-term outcomes.

References: ICH E8(R1).

NEW QUESTION # 18

In accordance with the ICH E2A Guideline, the sponsor must report an adverse event that is life-threatening, unexpected, and associated with the investigational drug to the regulatory authority as soon as possible but no later than how many calendar days after first knowledge of the event?

- A. 7 days
- B. 1 day
- C. 15 days
- D. 10 days

Answer: A

Explanation:

Serious adverse events are subject to expedited reporting requirements.

* ICH E2A 3.2.2:"Fatal or life-threatening unexpected ADRs should be reported as soon as possible but no later than 7 calendar days after first knowledge."

* ICH E2A 3.2.3: Other serious unexpected events must be reported within 15 days.

Thus, the 7-day rule applies to life-threatening and unexpected events (as in this case).

Correct answer: B (7 days).

References:

ICH E2A, §3.2.2.

NEW QUESTION # 19

If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. IRB/IEC immediately, then sponsor when full details are available
- B. Sponsor and IRB/IEC within five days
- C. Sponsor and IRB/IEC within seven days
- D. **Sponsor and IRB/IEC immediately, then update later**

Answer: D

Explanation:

* ICH E6(R2) 4.11.1: Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."

* IRB must also be informed promptly per 21 CFR 312.64(b).

* Follow-up information is submitted later as available.

References: ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 20

In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The site's accreditation certificate
- B. The site's SOPs
- C. The delegation of duties log
- D. **The IRB/IEC trial approval documentation**

Answer: D

Explanation:

* ICH E6(R2) 4.4.1: "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."

* Sponsors must confirm IRB approval before authorizing initiation.

References: ICH E6(R2), §4.4.1.

NEW QUESTION # 21

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