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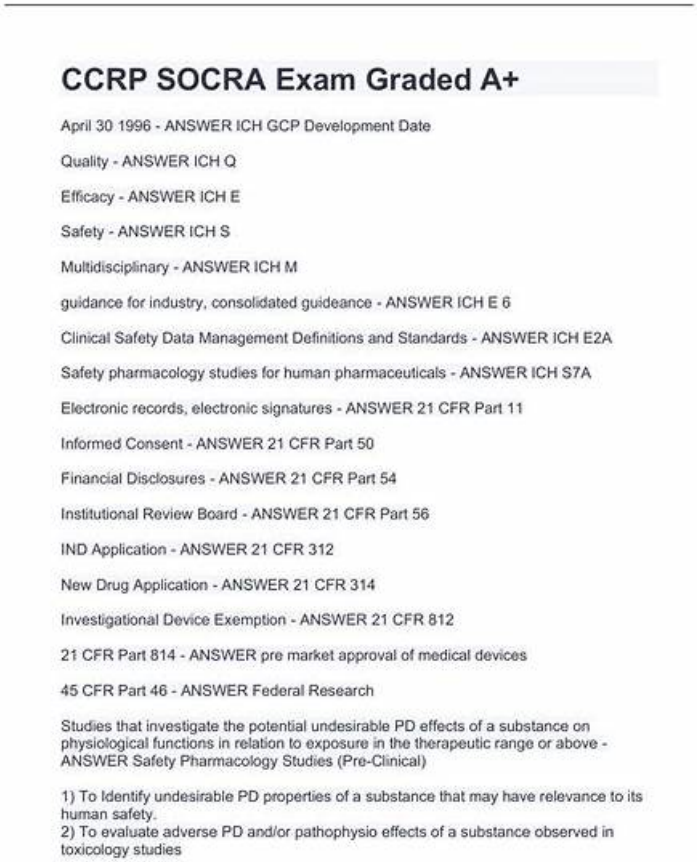

CCRP SOCRA Exam Graded A+

April 30 1996 - ANSWER ICH GCP Development Date

Quality - ANSWER ICH Q

Efficacy - ANSWER ICH E

Safety - ANSWER ICH S

Multidisciplinary - ANSWER ICH M

guidance for industry, consolidated guideance - ANSWER ICH E 6

Clinical Safety Data Management Definitions and Standards - ANSWER ICH E2A

Safety pharmacology studies for human pharmaceuticals - ANSWER ICH S7A

Electronic records, electronic signatures - ANSWER 21 CFR Part 11

Informed Consent - ANSWER 21 CFR Part 50

Financial Disclosures - ANSWER 21 CFR Part 54

Institutional Review Board - ANSWER 21 CFR Part 56

IND Application - ANSWER 21 CFR 312

New Drug Application - ANSWER 21 CFR 314

Investigational Device Exemption - ANSWER 21 CFR 812

21 CFR Part 814 - ANSWER pre market approval of medical devices

45 CFR Part 46 - ANSWER Federal Research

Studies that investigate the potential undesirable PD effects of a substance on physiological functions in relation to exposure in the therapeutic range or above - ANSWER Safety Pharmacology Studies (Pre-Clinical)

1) To Identify undesirable PD properties of a substance that may have relevance to its human safety.
2) To evaluate adverse PD and/or pathophysio effects of a substance observed in toxicology studies

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q60-Q65):

NEW QUESTION # 60
Which of the following statements about the investigator's brochure is correct?

- A. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans
- B. It consists of the instructions for the investigator to conduct the study
- C. It includes financial disclosure information from investigators
- D. It provides documents that permit the evaluation of the conduct of the study and the quality of the data

Answer: A

Explanation:
TheInvestigator's Brochure (IB)is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.
* ICH E6(R2) 7.1:Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."
* ICH E6(R2) 7.2.2:Specifies the IB should contain asummary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.
* The purpose is to allow investigators to makerisk-benefit assessments, support protocol design, and ensure subject safety.
Incorrect options:
* A (instructions to conduct study) describes theprotocol, not the IB.
* C (financial disclosures) are required under21 CFR 54, not part of the IB.
* D refers totrial master file/essential documents, not the IB.
Therefore, the IB's defining function is to provide ascientific summary of preclinical and clinical data supporting safe human use.
References:
ICH E6(R2), §7.1, §7.2.2.

NEW QUESTION # 61
A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related duties?

- A. The investigator/institution
- B. The external source
- C. The IRB/IEC
- D. The sponsor

Answer: A

Explanation:
The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff-regardless of employment source. Exact extracts:
* ICH E6(R2) 4.1.1: "The investigator should bequalified... and haveadequate resourcesto properly conduct the trial."
* ICH E6(R2) 4.1.5: "The investigatorshould ensure that all persons assistingwith the trial are adequately informedabout the protocol, the investigational product(s), and their trial-related duties and functions."
* ICH E6(R2) 4.2.5: "The investigatormay delegate... butretains responsibilityfor the conduct of the trial at the site."Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.
References:
ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).==========

NEW QUESTION # 62

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: B

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 # 63
A subject has creatinine 1.6 mg/dL, slightly above eligibility (#1.5). Investigator believes this is normal for size. When can subject be enrolled?

- A. After sponsor revises eligibility and IRB approves amendment
- B. After monitor approves deviation
- C. After repeat test confirms 1.6
- D. After investigator documents explanation in chart

Answer: A

Explanation:
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol approved by IRB/IEC."
* Deviations must not occur unless to eliminate hazard. Eligibility criteria cannot be overridden by investigator opinion.
Thus, enrollment requires protocol amendment and IRB approval.
References:ICH E6(R2), §4.5.1.

NEW QUESTION # 64
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. Ship under dangerous goods requirements
- C. Execute material transfer agreement
- D. Notify enrolled subjects

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 # 65
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