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CCRP Prep Latest Version with Complete Solutions

The goal of assessment is....? ✓✓Determine care, treatment, and services to meet the patient's initial and continuing needs.

The goal of intake is to: ✓✓Conduct a comprehensive initial assessment on each new patient and construct an individualized treatment plan based on assessment findings

What guidelines contribute to the basis of the recommendations presented today? ✓✓AHA/ACC 2016 Recommended Dietary Patterns

A waist circumference of \geq __ cm (__ inches) in males and \geq __ cm (__ inches) in females is considered at risk ✓✓102 cm (40.2 inches), 88 cm (34.6 inches)

Lifestyle programs designed to produce weight loss are most effective if they include ✓✓A structured PA program

Behavioral counseling or instruction on how to apply behavioral strategies to lose and maintain weight loss

A moderately reduced caloric diet

What's more, part of that DumpTorrent CCRP dumps now are free: <https://drive.google.com/open?id=14PB3WbghuzwSKkyJRJVDFikVo5xUziM7>

We can say that how many the CCRP certifications you get and obtain qualification certificates, to some extent determines your future employment and development, as a result, the CCRP exam guide is committed to helping you become a competitive workforce, let you have no trouble back at home. Actually, just think of our CCRP Test Prep as the best way to pass the CCRP exam is myopic. They can not only achieve this, but ingeniously help you remember more content at the same time.

SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">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	<ul style="list-style-type: none"> • 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.
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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q82-Q87):

NEW QUESTION # 82

A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase II
- B. Phase I
- C. Phase IV
- D. Phase III

Answer: A

Explanation:

Phase classification is based on study objectives, not just subject numbers.

* Phase I: Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.

* Phase II: Evaluates effectiveness in patients with the condition and monitors common short-term side effects.

* Phase III: Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.

* Phase IV: Post-marketing studies exploring new indications, long-term safety, or special populations.

The given study aims to evaluate effectiveness and common short-term side effects in 30 arthritis patients, which clearly aligns with Phase II objectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).

Thus, the correct answer is B (Phase II).

References:

FDA Guidance: The IND Application - §312.21 (Phases of an investigation).

ICH E8(R1), General Considerations for Clinical Studies.

NEW QUESTION # 83

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 a drug/device accountability calculation question, testing compliance with investigational product tracking.

* The subject was instructed to perform 4 glucose checks per day.

* Over 10 days, that equals 40 tests ($4 \times 10 = 40$).

* Each test requires 1 strip, so 40 strips used.

* Subject was given 45 strips, leaving 5 unused after 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 is B (5 unused test strips).

References:

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

NEW QUESTION # 84

In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. The clinical investigator
- B. A data safety monitoring board
- C. The medical monitor
- **D. The reviewing IRB/IEC**

Answer: D

Explanation:

Minimal risk determination is a regulatory function of the IRB/IEC.

* 45 CFR 46.102(j): Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.

* 45 CFR 46.109(a): The IRB has authority to approve, require modifications, or disapprove research, including assessment of risk level.

* Investigators may propose a study as minimal risk, but only the IRB/IEC can formally classify it.

This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.

References: 45 CFR 46.102(j), 46.109(a).

NEW QUESTION # 85

A sponsor's monitor is conducting a site selection visit for an interventional drug trial. In accordance with ICH GCP, which pharmacy drug storage facility information should be collected in order to determine whether the site could be selected for the trial?

- A. Available storage square footage
- **B. Storage facility temperature range**
- C. Number of staff members
- D. Storage cost

Answer: B

Explanation:

Drug storage conditions are essential to maintaining investigational product (IP) integrity. According to ICH:

* ICH E6(R2) 5.13.3: "The sponsor should ensure that investigational products are stored... under appropriate conditions as specified by the sponsor and in accordance with applicable regulatory requirement(s)."

* ICH E6(R2) 4.6.4: "The investigator/institution should store the investigational product(s) as specified by the sponsor (and in

accordance with applicable regulatory requirement(s)), and ensure that product (s) are used only in accordance with the approved protocol." During site qualification/selection, the monitor evaluates storage conditions - particularly temperature ranges- to ensure the site can meet the stability requirements for the IP. Factors like staff numbers, space, and cost are operational considerations but not regulatory determinants of site qualification.

Thus, the correct answer is C (Storage facility temperature range). This ensures compliance with sponsor specifications, product stability, and ultimately subject safety.

References:

ICH E6(R2), §5.13.3 (Product storage requirements).

ICH E6(R2), §4.6.4 (Investigator product storage responsibilities).

NEW QUESTION # 86

According to 21 CFR Part 11, each electronic signature must be unique and:

- A. Cannot be reused or reassigned
- B. Identical to handwritten signature
- C. Transferable to family
- D. Reassignable after validation

Answer: A

Explanation:

* 21 CFR 11.100(a): Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone else."

* This ensures accountability and audit trail integrity.

References: 21 CFR 11.100(a).

NEW QUESTION # 87

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