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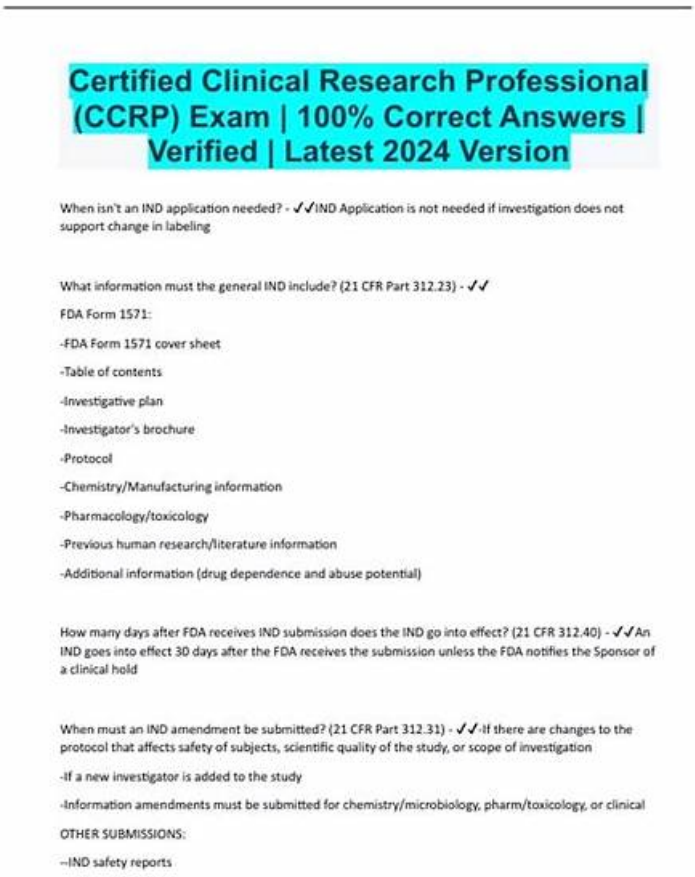

Certified Clinical Research Professional (CCRP) Exam | 100% Correct Answers | Verified | Latest 2024 Version

When isn't an IND application needed? - ✓✓IND Application is not needed if investigation does not support change in labeling

What information must the general IND include? (21 CFR Part 312.23) - ✓✓

FDA Form 1571:

-FDA Form 1571 cover sheet

-Table of contents

-Investigative plan

-Investigator's brochure

-Protocol

-Chemistry/Manufacturing information

-Pharmacology/toxicology

-Previous human research/literature information

-Additional information (drug dependence and abuse potential)

How many days after FDA receives IND submission does the IND go into effect? (21 CFR 312.40) - ✓✓An IND goes into effect 30 days after the FDA receives the submission unless the FDA notifies the Sponsor of a clinical hold

When must an IND amendment be submitted? (21 CFR Part 312.31) - ✓✓-If there are changes to the protocol that affects safety of subjects, scientific quality of the study, or scope of investigation

-If a new investigator is added to the study

-Information amendments must be submitted for chemistry/microbiology, pharm/toxicology, or clinical

OTHER SUBMISSIONS:

--IND safety reports

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	• 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.
Topic 2	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q104-Q109):

NEW QUESTION # 104
In accordance with the ICH GCP Guideline, at what intervals should the on-site study monitoring be performed?

- A. At least weekly
- B. Every 4-6 weeks until study close-out
- C. In a timely manner before, during, and after the study
- D. Once a year until study close-out

Answer: C

Explanation:
Monitoring ensures trial integrity and subject safety.
* ICH E6(R2) 5.18.3:"The sponsor should ensure that the trials are adequately monitored. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial."
* Monitoring must occurbefore (initiation visit), during (periodic), and after (closeout).
It is not limited to fixed weekly or monthly intervals (A, B) and not as infrequent as yearly (D). Instead, it is risk-adapted and flexible, but must cover all phases of the study.
Correct answer:C (Timely manner before, during, and after).
References:
ICH E6(R2), §5.18.3.

NEW QUESTION # 105
Upon completion of a study, the investigator should do which of the following?

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

Answer: A

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 # 106
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. Financial reports
- C. Standard Operating Procedures (SOPs)
- 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 ofquality 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 # 107
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: D

Explanation:
This is adrug/device accountability calculation question, testing compliance with investigational product tracking.
* The subject was instructed to perform4 glucose checks per day.
* Over10 days, that equals40 tests (4 × 10 = 40).

* Each test requires1 strip, so40 strips used.
* Subject was given45 strips, leaving5 unusedafter 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 isB (5 unused test strips).
References:
ICH E6(R2), §4.6.3 (Investigational product accountability).

NEW QUESTION # 108
In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

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

Answer: B

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 # 109
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