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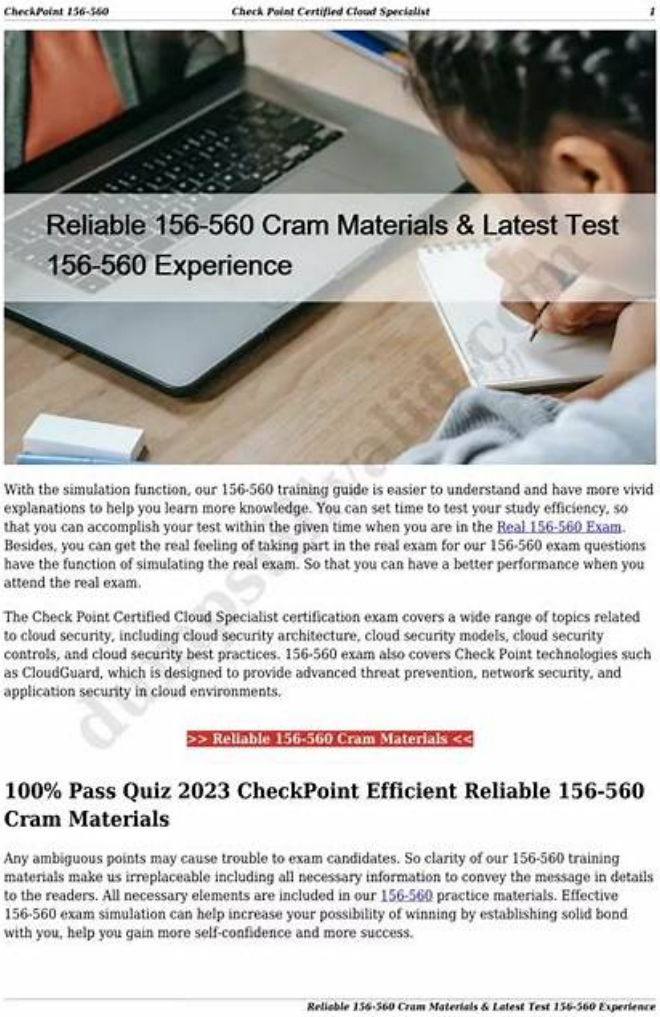

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SOCRA CCRP Exam Syllabus Topics:

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q95-Q100):

NEW QUESTION # 95
Which of the following is an example of an additional protection required when conducting research on children?

- A. Parents must be present during all procedures
- B. The investigator must obtain age-appropriate assent as determined by the IRB/IEC
- C. There must be an impartial advocate present during the consent process
- D. The study must be approved by a central pediatric IRB

Answer: B

Explanation:
Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and howassent is obtained, in addition to parental permission. Exact extracts:
* 45 CFR 46.408(a): "The IRB shall determine...whether and to what extent children are capable of providing assent."
* ICH E6(R2) 4.8.12: "Where a subject is unable to give consent personally,assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s)."Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.
References:
ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).
45 CFR 46 Subpart D-Additional Protections for Children, §46.408(a).==========

NEW QUESTION # 96
In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

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

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 # 97
On 15 May 2019, a sponsor announced that its investigational compound GHB33IA will not be investigated any further and will not be pursued for a marketing approval. According to the CFR, what is the earliest date when the site may begin to destroy the study records?

- A. 15 May 2022
- B. 15 May 2034
- C. 16 May 2022
- D. 16 May 2021

Answer: C

Explanation:
Record retention requirements ensure regulatory access to data even after development is discontinued.
* 21 CFR 312.62(c):"An investigator shall retain records... for2 years after the date a marketing application is withdrawn or discontinuedand FDA is notified."
* In this case, development was terminated15 May 2019. Therefore, the 2-year clock starts at discontinuation. Two years later is15 May 2021, but FDA requires records to be maintaineduntil after the 2-year period ends. Theearliest permissible destruction date is 16 May 2022 (C).
Options A and B are premature; D (2034) is far beyond requirements.
Thus, the correct answer isC (16 May 2022).
References:
21 CFR 312.62(c) (Investigator record retention).
21 CFR 312.57(c) (Sponsor record retention).

NEW QUESTION # 98
Which countries have officially adopted ICH-GCP E6(R2) as a standard, in addition to U.S., EU, Japan, Canada, and Australia?

- A. Switzerland
- B. China
- C. Brazil
- D. India

Answer: D

Explanation:
India has aligned national regulations with ICH-GCP.

* DCGI/ICMR Guidelines (India):Explicitly adopt ICH E6(R2) as part of its Good Clinical Practice standards.China and Brazil are harmonizing, but full official adoption is noted in India.
References:Indian GCP Guidelines (2017 revision).

NEW QUESTION # 99
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 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
- B. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure
- C. Death due to disease progression, mentioned in the investigator's brochure
- D. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy

Answer: A

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 # 100
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