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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 (Q98-Q103):

NEW QUESTION # 98

For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 2 working days
- B. 5 working days
- C. 10 working days
- D. 7 working days

Answer: C

Explanation:

In device trials, unanticipated adverse device effects (UADEs) must be promptly reported.

* 21 CFR 812.150(a)(1): "An investigator shall submit to the sponsor and the reviewing IRB a report of any unanticipated adverse device effect as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect." In this case, severe burns with blistering go beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as a UADE and triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a 10 working day maximum timeframe.

Thus, the correct answer is D (10 working days).

References:

21 CFR 812.150(a)(1) (Reporting requirements for investigators).

NEW QUESTION # 99

Which of the following would be considered an addendum to an investigator's brochure for an unapproved Investigational Product?

- A. Product monograph updates
- B. A Suspected Unexpected Serious Adverse Reaction (SUSAR) report
- C. A site-specific SAE report
- D. Revisions to the risk section of the informed consent form

Answer: B

Explanation:

The IB must be updated as new significant safety information emerges.

* ICH E6(R2) 7.3: "The sponsor should revise the IB as soon as new, significant information becomes available."

* ICH E2A: Requires sponsors to report Suspected Unexpected Serious Adverse Reactions (SUSARs) in expedited reports and include them in IB updates or addenda.

A SUSAR report (B) represents new, unexpected, and serious safety information not previously documented, and therefore warrants inclusion as an IB addendum until the IB is formally updated.

Revised consent forms (A) are submitted to IRBs, not IBs. Site-specific SAE reports (C) remain at site /sponsor level, not in the IB. Product monograph updates (D) apply to approved products, not investigational ones. Thus, the correct answer is B (SUSAR report).

References:

ICH E6(R2), §7.3 (Updating the Investigator's Brochure).

ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

NEW QUESTION # 100

Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Ensuring that all participating investigators are promptly informed of significant new adverse events
- B. Ensuring proper monitoring of an investigation at all investigational sites
- C. Maintaining control of the investigational product
- D. Reporting serious adverse events to the applicable regulatory agency

Answer: C

Explanation:

For non-sponsor investigators, responsibilities are limited to site-level conduct and product accountability.

* ICH E6(R2) 4.6.1: "Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."

* 21 CFR 312.61: Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.

Other responsibilities listed belong to sponsors:

* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).

* B: Monitoring at all sites is a sponsor responsibility.

* C: Disseminating safety updates is a sponsor's role.

Correct answer: D (Maintaining control of IP).

References:

ICH E6(R2), §4.6.1.

21 CFR 312.61.

NEW QUESTION # 101

The sponsor discontinued the clinical development of an investigational product. In accordance with the ICH GCP Guidance, at least how long should the sponsor maintain all sponsor-specific essential documents?

- A. 15 years
- B. 2 years
- C. 3 years
- D. 5 years

Answer: B

Explanation:

Retention of essential documents ensures accountability and inspection readiness.

* ICH E6(R2) 5.5.12 & 8.1: Sponsors should retain essential documents "until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications or at least 2 years after formal discontinuation of clinical development of the investigational product." This standard balances subject protection with practical recordkeeping. Longer durations (B-D) may apply under institutional or national rules, but ICH establishes 2 years minimum.

Correct answer: A (2 years).

References:

ICH E6(R2), §5.5.12, §8.1.

NEW QUESTION # 102

In accordance with ICH, which of the following is an acceptable protocol review frequency for an IRB?

