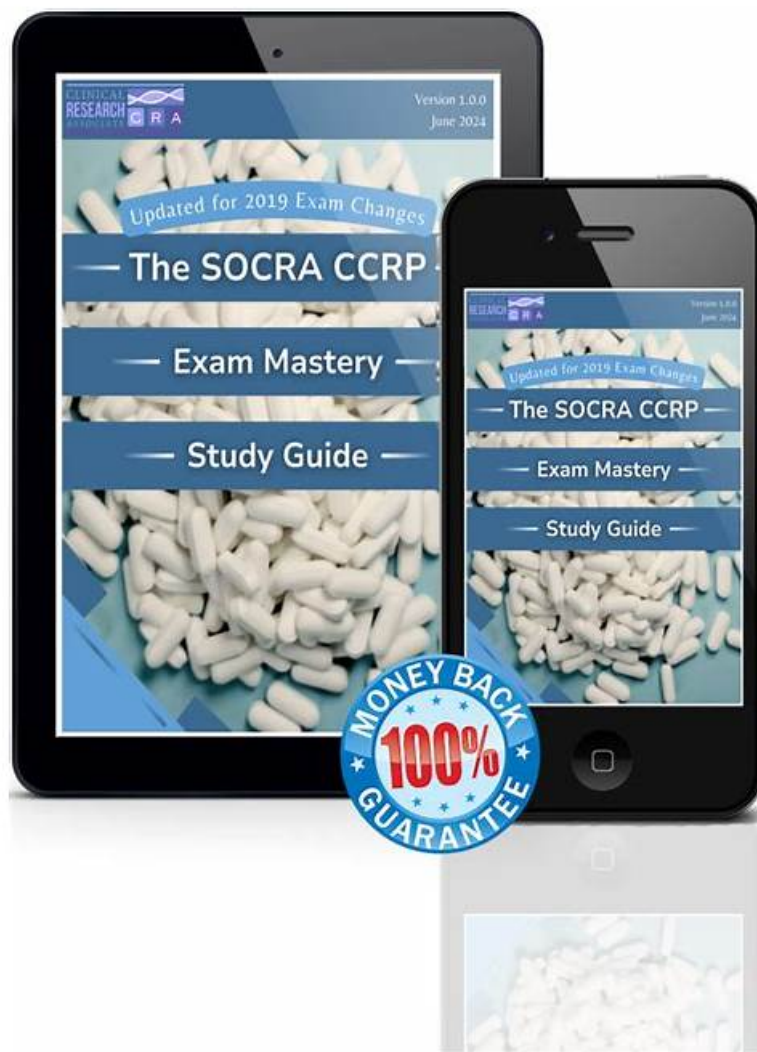


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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q103-Q108):

NEW QUESTION # 103

The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission. According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- A. Case report forms
- B. Local lab normal ranges
- C. The investigators' CVs
- **D. Recruitment materials**

Answer: D

Explanation:

IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.

* ICH E6(R2) 3.1.2: The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.

* 21 CFR 56.111(a)(3): Requires equitable subject selection, which extends to advertisements and recruitment.

* FDA Guidance on Recruiting Study Subjects (1998): States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.

Correct answer: C (Recruitment materials).

References:

ICH E6(R2), §3.1.2.

FDA Recruitment Guidance, 1998.

NEW QUESTION # 104

In accordance with the ICH GCP Guideline, prior to initiating a trial, which of the following should define, establish, and allocate all trial-related duties and functions?

- **A. The sponsor**
- B. The study coordinator
- C. The IRB/IEC
- D. The institutional administrator

Answer: A

Explanation:

* ICH E6(R2) 5.2.1: "The sponsor is responsible for implementing and maintaining quality assurance and quality control systems... including allocation of trial-related duties."

* Although tasks may be delegated to CROs or site staff, accountability remains with the sponsor.

References: ICH E6(R2), §5.2.1.

NEW QUESTION # 105

Why would a Phase IV study be conducted?

- **A. Different off-label population**
- B. Different schedule of administration
- C. Different marketing strategy
- D. Different dosage

Answer: A

Explanation:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

* ICH E8(R1): Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

* They often test drugs in new or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses on new patient populations or long-term outcomes.
References: ICH E8(R1).

NEW QUESTION # 106

According to the ICH GCP Guidelines, what is the purpose of source documents?

- A. To validate reports submitted to the IRB/IEC
- B. To establish diverse subject enrollment
- **C. To provide a record of subjects' investigational medical treatment**
- D. To validate insurance reimbursement

Answer: C

Explanation:

* ICH E6(R2) 1.52: Source documents are "original documents, data, and records... necessary for the reconstruction and evaluation of the trial."

* Their main role is to document treatment and verify CRFs.

References: ICH E6(R2), §1.52.

NEW QUESTION # 107

If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC within five days
- B. Sponsor and IRB/IEC within seven days
- C. IRB/IEC immediately, then sponsor when full details are available
- **D. Sponsor and IRB/IEC immediately, then update later**

Answer: D

Explanation:

* ICH E6(R2) 4.11.1: Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."

* IRB must also be informed promptly per 21 CFR 312.64(b).

* Follow-up information is submitted later as available.

References: ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 108

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