

ACRP-CP日本語復習赤本、ACRP-CP合格体験談



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>> ACRP-CP日本語復習赤本 <<

ACRP-CP合格体験談、ACRP-CP出題内容

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ACRP Certified Professional Exam 認定 ACRP-CP 試験問題 (Q36-Q41):

質問 #36

When assessing the monitoring needs for a study, sponsors should:

- A. Ensure monitors have the scientific and/or clinical knowledge needed to monitor the trial adequately.
- B. Ensure monitoring visits are conducted at periodic intervals with a minimum of monthly monitoring visits.
- C. Permit PIs to select a monitor for their site as long as they are independent of the PI.
- D. Use central monitoring instead of conducting physical monitoring visits at sites.

正解: A

解説:

Sponsors must ensure that monitors are adequately qualified, possessing the necessary scientific and clinical knowledge to effectively oversee the trial. This ensures that monitors can accurately assess protocol compliance, data integrity, and participant safety. The quality of monitoring directly impacts the credibility of the trial outcomes.

GCP guidelines specify that monitors must be adequately trained and knowledgeable about the trial protocol, investigational product (IP), and clinical research standards.

"The sponsor must ensure that monitors have appropriate qualifications and training to conduct effective trial monitoring." Objectives:

- * Maintain data integrity through skilled monitoring.
- * Ensure patient safety and protocol compliance.

質問 # 37

A clinical trial where participants will be randomized to receive a sequence of two medications has which design configuration?

- A. Group sequential
- B. Factorial
- C. Parallel Group
- D. Crossover

正解: D

解説:

A crossover study design involves participants receiving multiple interventions sequentially, with a washout period in between to minimize carryover effects. This design allows each participant to serve as their own control, increasing statistical power while reducing variability. It is commonly used when comparing two treatments or interventions.

GCP guidelines classify a crossover design as one where subjects receive multiple treatments in a specified sequence.

"In crossover trials, participants receive each intervention in a specific order, allowing for within-subject comparison." Objectives:

- * Understand the structure of crossover studies.
- * Improve statistical efficiency through self-control comparisons.

質問 # 38

A representative from a regulatory authority shows up unannounced at a research site. After confirming their credentials, the representative requested to view the entire records, including identifiable information, from study XYZ that was closed out. Which of the following should the site personnel do next?

- A. Consult with the IRB/IEC first.
- B. Redact subject identification for privacy protection.
- C. Allow access to the entire records.
- D. Deny the request until the sponsor approves.

正解: C

解説:

Regulatory authorities have the legal right to inspect clinical trial records, including identifiable information, even if the study has been closed out. After verifying the inspector's credentials, the site personnel must grant access to all requested documents to ensure compliance with regulations.

According to GCP guidelines, regulatory authorities have the right to access trial-related documents and data during inspections.

"Investigators must grant access to study records when requested by regulatory authorities as part of their inspection rights."

Objectives:

- * Ensure compliance with inspection requirements.
- * Maintain transparency with regulatory authorities.

質問 # 39

A double-blind randomized Phase III trial seeks to recruit 500 subjects in 2 years. At the end of the first year, 150 subjects have been enrolled. Monitoring reports from the first year note 50% of subjects screened were screen failures due to exclusionary lab values. What action should the sponsor take?

- A. Reduce the target sample size based on feedback from the sites.
- **B. Evaluate the screen failures to determine if the protocol needs revision.**
- C. Re-train investigators on recruitment obligations.
- D. Allocate additional monitoring resources to the trial.

正解: B

解説:

The high rate of screen failures indicates that the inclusion/exclusion criteria may be too stringent or not appropriately defined. The sponsor should evaluate the reasons for these failures and determine whether the protocol needs adjustment. Revising the criteria may increase recruitment efficiency without compromising the scientific validity of the study.

GCP guidelines advise reviewing and possibly revising protocols when screen failure rates are significantly high to ensure feasible recruitment.

"If a high number of screen failures occurs, the sponsor should evaluate the inclusion/exclusion criteria and consider protocol revisions." Objectives:

- * Improve recruitment efficiency.
- * Adapt protocol criteria to real-world conditions.

質問 # 40

A study has been closed for two years after the last approval of a marketing application of an IP. No additional applications are pending and there are no further developments planned for the IP. Which of the following statements is the BEST course of action regarding the destruction of the essential documents?

- A. The site should contact the sponsor and receive verbal notification they are no longer needed and the essential documents may be destroyed.
- B. The site should retain the essential documents longer to meet the regulatory requirements.
- C. The site may proceed with the destruction of the essential documents.
- **D. The site should contact the sponsor and receive written notification prior to destruction that the essential documents are no longer needed.**

正解: D

解説:

Before destroying any essential documents, the site must obtain written confirmation from the sponsor that these documents are no longer needed. This ensures compliance with regulatory requirements, as some countries may require document retention for longer periods, even after study closure and marketing approval.

GCP guidelines state that the sponsor must confirm in writing that essential documents can be destroyed after ensuring compliance with local regulations.

"Before destroying essential documents, written confirmation from the sponsor is required to ensure compliance with regulatory retention policies." Objectives:

- * Maintain compliance with document retention regulations.
- * Prevent premature destruction of essential trial records.

質問 # 41

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ACRP-CP合格体験談: <https://www.xhs1991.com/ACRP-CP.html>

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