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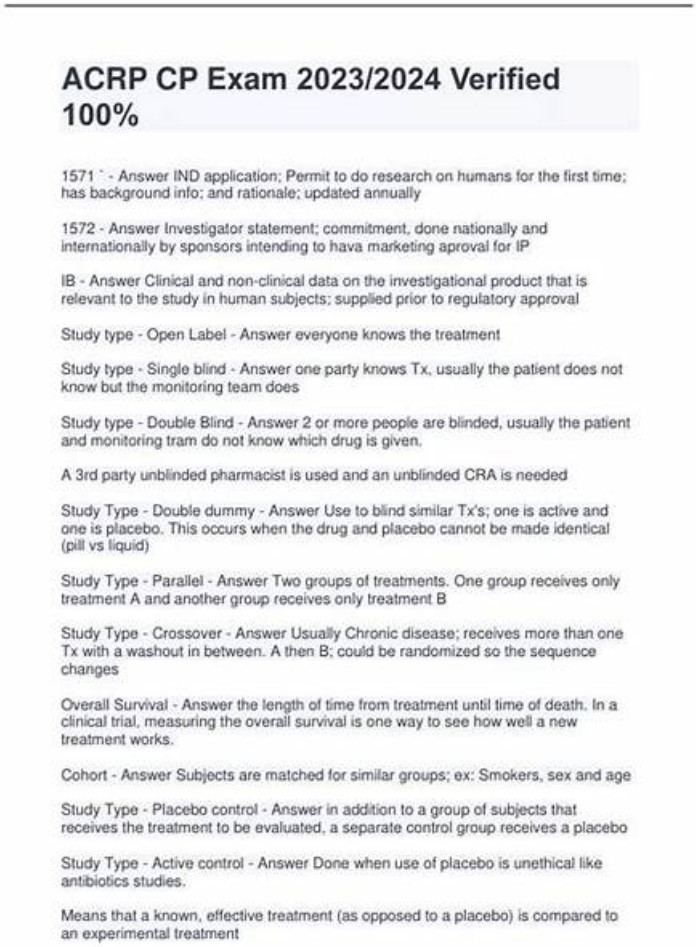

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1571 ˆ - Answer IND application; Permit to do research on humans for the first time; has background info; and rationale; updated annually

1572 - Answer Investigator statement; commitment, done nationally and internationally by sponsors intending to hava marketing aproval for IP

IB - Answer Clinical and non-clinical data on the investigational product that is relevant to the study in human subjects; supplied prior to regulatory approval

Study type - Open Label - Answer everyone knows the treatment

Study type - Single blind - Answer one party knows Tx, usually the patient does not know but the monitoring team does

Study type - Double Blind - Answer 2 or more people are blinded, usually the patient and monitoring tram do not know which drug is given.

A 3rd party unblinded pharmacist is used and an unblinded CRA is needed

Study Type - Double dummy - Answer Use to blind similar Tx's; one is active and one is placebo. This occurs when the drug and placebo cannot be made identical (pill vs liquid)

Study Type - Parallel - Answer Two groups of treatments. One group receives only treatment A and another group receives only treatment B

Study Type - Crossover - Answer Usually Chronic disease; receives more than one Tx with a washout in between. A then B; could be randomized so the sequence changes

Overall Survival - Answer the length of time from treatment until time of death. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works.

Cohort - Answer Subjects are matched for similar groups; ex: Smokers, sex and age

Study Type - Placebo control - Answer in addition to a group of subjects that receives the treatment to be evaluated, a separate control group receives a placebo

Study Type - Active control - Answer Done when use of placebo is unethical like antibiotics studies.

Means that a known, effective treatment (as opposed to a placebo) is compared to an experimental treatment

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ACRP Certified Professional Exam Sample Questions (Q121-Q126):

NEW QUESTION # 121
Confidentiality and privacy rules for protection of human subjects at research sites are determined by the:

- A. Applicable regulatory authorities
- B. Applicable site SOPs
- C. PI
- D. Sponsor

Answer: A

Explanation:
The confidentiality and privacy rules protecting human subjects in clinical research are established by applicable regulatory authorities, such as the FDA or EMA, and must be followed by all research sites. These regulations ensure that participants' personal data are handled securely and ethically.
GCP guidelines mandate compliance with local, national, and international regulations regarding data confidentiality and privacy. "Confidentiality and privacy protections are determined by applicable regulatory authorities and must be adhered to by all study sites." Objectives:
* Protect participant privacy.
* Ensure compliance with data protection regulations.

NEW QUESTION # 122
Who is responsible to ensure training for key staff members unable to attend the site initiation visit?

- A. Investigator
- B. Monitor
- C. Sponsor
- D. Coordinator

Answer: A

Explanation:
The Principal Investigator (PI) is responsible for ensuring that all site staff involved in the study are adequately trained, even if they were unable to attend the Site Initiation Visit (SIV). This responsibility includes organizing training sessions or providing relevant training materials to maintain consistency and compliance with study protocols.
According to GCP guidelines, the PI must ensure that all staff members involved in the trial are adequately informed and trained on their specific responsibilities.
"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions." Objectives:
* Maintain consistent training for all clinical staff.
* Ensure compliance with study procedures.

NEW QUESTION # 123
Which of the following activities is the MOST efficient way of overseeing a CRO's management during a clinical trial?

- A. Pre-qualification assessment of CRO
- B. Central monitoring of data fields by sponsor
- C. Co-monitoring of CRO site visits
- D. Risk-based audits of CRO activities as delegated

Answer: D

Explanation:
Risk-based audits of CRO activities as delegated are considered the most efficient way of overseeing a CRO's management. This

approach focuses on evaluating the critical risks that might impact data integrity and participant safety. It allows sponsors to allocate resources to areas with the highest potential for error or deviation, rather than performing exhaustive monitoring of all activities.
The answer is verified as per guidelines on risk-based monitoring strategies, emphasizing targeted and efficient oversight of CRO functions.
"Risk-based monitoring emphasizes focusing on critical study parameters and the risks that have the potential to affect data quality and subject safety." Objectives:
* Efficient management of outsourced clinical trial tasks.
* Ensuring data integrity through targeted audits.

NEW QUESTION # 124
Preliminary evidence suggests a low-dose anti-cancer drug given for a short period of time may reduce the risk of developing cancer in patients who are at increased risk for developing cancer. The drug has potentially serious side effects. What is the MOST important question to consider before designing a clinical trial to test this hypothesis?

- A. How willing are current patients to participate in a trial with potentially serious side effects?
- B. How likely are patients at high risk of cancer going to develop cancer during the study?
- C. How does the risk of developing cancer compare to the anticipated side effects from the drug?
- D. How effective is the drug at treating patients that have been previously diagnosed with cancer?

Answer: C

Explanation:
Before initiating a clinical trial with a drug that has potentially serious side effects, it is essential to evaluate the risk-benefit ratio. The primary consideration is whether the potential benefits (reduced cancer risk) outweigh the risks (serious side effects). This assessment is fundamental to ethical clinical trial design.
The answer is verified as per GCP and ethical guidelines, which require a thorough assessment of risk versus benefit before conducting human trials.
"An assessment of potential benefits versus risks is a fundamental principle in the ethical design of clinical trials, especially when potential adverse effects are severe." Objectives:
* Ensure ethical considerations in trial design.
* Assess the potential harm versus benefit to participants.

NEW QUESTION # 125
An audit was recently completed and identified non-compliance that could potentially affect the reliability of study results. Who should perform a root cause analysis and implement appropriatecorrective and preventive actions?

- A. IRB/IEC
- B. DSMB/IDMC
- C. Sponsor
- D. PI

Answer: D

Explanation:
The Principal Investigator (PI) is responsible for conducting a root cause analysis when non-compliance is identified at the site. The PI must identify the reasons for non-compliance and develop a Corrective and Preventive Action (CAPA) plan to address and prevent future occurrences.
This answer aligns with GCP principles that designate the PI as responsible for site-level compliance and corrective actions.
"The PI must take responsibility for investigating the cause of non-compliance and developing a CAPA plan to mitigate recurrence." Objectives:
* Maintaining compliance and data integrity
* Addressing non-compliance proactively

NEW QUESTION # 126
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