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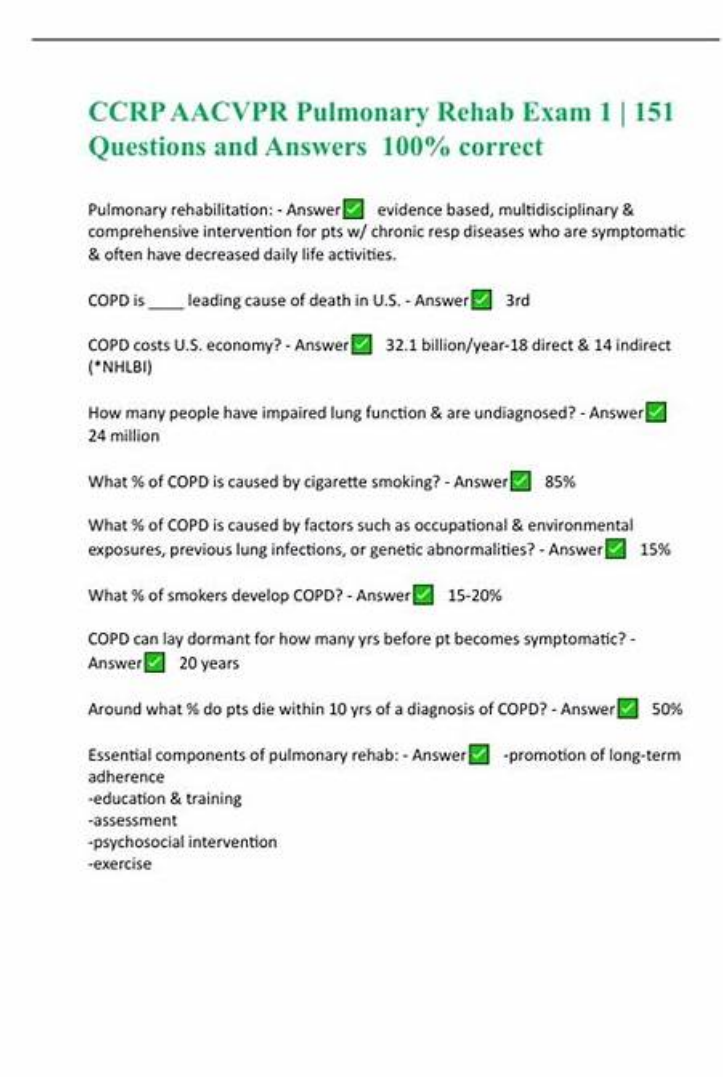

CCRP AACVPR Pulmonary Rehab Exam 1 | 151 Questions and Answers 100% correct

Pulmonary rehabilitation: - Answer ✅ evidence based, multidisciplinary & comprehensive intervention for pts w/ chronic resp diseases who are symptomatic & often have decreased daily life activities.

COPD is ____ leading cause of death in U.S. - Answer ✅ 3rd

COPD costs U.S. economy? - Answer ✅ 32.1 billion/year-18 direct & 14 indirect (*NHLBI)

How many people have impaired lung function & are undiagnosed? - Answer ✅ 24 million

What % of COPD is caused by cigarette smoking? - Answer ✅ 85%

What % of COPD is caused by factors such as occupational & environmental exposures, previous lung infections, or genetic abnormalities? - Answer ✅ 15%

What % of smokers develop COPD? - Answer ✅ 15-20%

COPD can lay dormant for how many yrs before pt becomes symptomatic? - Answer ✅ 20 years

Around what % do pts die within 10 yrs of a diagnosis of COPD? - Answer ✅ 50%

Essential components of pulmonary rehab: - Answer ✅ -promotion of long-term adherence
-education & training
-assessment
-psychosocial intervention
-exercise

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	• 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.
Topic 2	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q77-Q82):

NEW QUESTION # 77
An investigator discovered a new serious unanticipated adverse device effect. Who must they notify?

- A. OHRP
- B. FDA
- C. Sponsor
- D. Research pharmacist

Answer: C

Explanation:
* 21 CFR 812.150(a)(1):Investigators must report unanticipated adverse device effects to thesponsor within 10 working days.
* Sponsor is then responsible for notifying FDA and all investigators.
References:21 CFR 812.150(a)(1).

NEW QUESTION # 78
In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The quality control specialist
- B. The contract research organization monitor

- C. The IRB/IEC coordinator
- D. The clinical investigator

Answer: D

Explanation:
The investigator holds ultimate responsibility for all data reported.
* ICH E6(R2) 4.9.1:"The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."
* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.
Correct answer:A (The clinical investigator).
References:
ICH E6(R2), §4.9.1.

NEW QUESTION # 79
In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties andfunctions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The sponsor
- B. The IRB/IEC
- C. The investigator
- D. The CRO

Answer: A

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."Hence, D is correct.
References:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).==========

NEW QUESTION # 80
In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Justice
- B. Do no harm
- C. Respect for persons
- D. Beneficence

Answer: C

Explanation:
TheBelmont Report (1979)establishedthree key ethical principles:
* Respect for Persons:Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.
* Beneficence:Obligation to maximize benefits and minimize harm.
* Justice:Ensuring fairness in subject selection and distribution of research burdens/benefits.
Voluntary informed consent embodiesRespect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.
Thus, the correct answer isB (Respect for persons).
References:
The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 81
According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

- A. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness
- B. The subject or else the subject's legally authorized representative
- C. The subject or else the subject's legally authorized representative; the witness
- D. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee

Answer: C

Explanation:
Theshort form consent processis permitted when the subject is presented with a brief written statement that they were informed of the study, supplemented by an oral presentation.
* 21 CFR 50.27(b)(2):Requires the short form to be signed by the subject (or legally authorized representative)and a witness.
* The witness ensures that oral consent was properly conveyed and understood.
* The person obtaining consent must sign aseparate written summary, but not the short form itself.
Thus, the accurate answer isA: subject (or LAR) + witness.
References:
21 CFR 50.27(b)(2).

NEW QUESTION # 82
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