
Practice Questions for SOCRA exam| 105 QUESTIONS| WITH COMPLETE SOLUTIONS

Which of the following is a disclosure of financial interests form? Correct Answer:

Which of the following is a certification of financial interest form? Correct Answer:

If the investigator did have financial arrangement with the sponsor, he/she would submit the following form: Correct Answer:

This form is submitted by sponsor to the FDA prior to the beginning of the drug trial Correct Answer: Investigational New Drug Application

In the top right corner, form have OMB number. What does it stand for? Correct Answer:

The form, which is submitted to the FDA to report an Adverse Event is Correct Answer:

Medical device adverse events/problems are reported via a form: Correct Answer:

What is FDA form 1571? Correct Answer:

21 CFR 312 deals with Correct Answer:

Investigational new drug means Correct Answer: A new drug or biological drug that is used in a clinical investigation

The immediate package of an investigational new drug intended for human use shall bear a label with the statement Correct Answer:

Which of the following is not listed on FDA form 1571: Correct Answer: a. name, address, phone number of the sponsor
b. a commitment not to start the clinical investigation until the IND is in effect
c. identification of the phase of the trial
d. approved informed consent document

"Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred" Is... Correct Answer: a. serious adverse drug experience
b. life threatening adverse drug experience
c. none of the above

What are the three main basic ethical principles of the Belmont Report? Correct Answer: 1. Respect for Persons
2. Beneficence
3. Justice

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RM Cervero

A red circular graphic with a gradient, appearing as a semi-circle or a partial circle, located to the right of the 'RM Cervero' text.

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Table of Contents Socra Exam Questions

1. Understanding the eBook Socra Exam Questions
 - The Rise of Digital Reading Socra Exam Questions
 - Advantages of eBooks Over Traditional Books
2. Identifying Socra Exam Questions
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Socra Exam Questions
 - User-Friendly Interface
4. Exploring eBook Recommendations from Socra Exam Questions
 - Personalized Recommendations
 - Socra Exam Questions User Reviews and Ratings
 - Socra Exam Questions and Bestseller Lists
5. Accessing Socra Exam Questions Free and Paid eBooks
 - Socra Exam Questions Public Domain eBooks
 - Socra Exam Questions eBook Subscription Services
 - Socra Exam Questions Budget-Friendly Options

6. Navigating Socra Exam Questions eBook Formats
 - ePub, PDF, MOBI, and More
 - Socra Exam Questions Compatibility with Devices
 - Socra Exam Questions Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Socra Exam Questions
 - Highlighting and Note-Taking Socra Exam Questions
 - Interactive Elements Socra Exam Questions
8. Staying Engaged with Socra Exam Questions
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Socra Exam Questions
9. Balancing eBooks and Physical Books Socra Exam Questions
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Socra Exam Questions
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Socra Exam Questions
 - Setting Reading Goals Socra Exam Questions
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Socra Exam Questions
 - Fact-Checking eBook Content of Socra Exam Questions
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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