

SOCRA CCRP PRACTICE EXAM (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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Introduction

Preparing for a certification exam can feel overwhelming, but with the right tools, it becomes an opportunity to build confidence, sharpen your skills, and move one step closer to your goals. At Examzify, we believe that effective exam preparation isn't just about memorization, it's about understanding the material, identifying knowledge gaps, and building the test-taking strategies that lead to success.

This guide was designed to help you do exactly that.

Whether you're preparing for a licensing exam, professional certification, or entry-level qualification, this book offers structured practice to reinforce key concepts. You'll find a wide range of multiple-choice questions, each followed by clear explanations to help you understand not just the right answer, but why it's correct.

The content in this guide is based on real-world exam objectives and aligned with the types of questions and topics commonly found on official tests. It's ideal for learners who want to:

- Practice answering questions under realistic conditions,
- Improve accuracy and speed,
- Review explanations to strengthen weak areas, and
- Approach the exam with greater confidence.

We recommend using this book not as a stand-alone study tool, but alongside other resources like flashcards, textbooks, or hands-on training. For best results, we recommend working through each question, reflecting on the explanation provided, and revisiting the topics that challenge you most.

Remember: successful test preparation isn't about getting every question right the first time, it's about learning from your mistakes and improving over time. Stay focused, trust the process, and know that every page you turn brings you closer to success.

Let's begin.

How to Use This Guide

This guide is designed to help you study more effectively and approach your exam with confidence. Whether you're reviewing for the first time or doing a final refresh, here's how to get the most out of your Examzify study guide:

1. Start with a Diagnostic Review

Skim through the questions to get a sense of what you know and what you need to focus on. Your goal is to identify knowledge gaps early.

2. Study in Short, Focused Sessions

Break your study time into manageable blocks (e.g. 30 – 45 minutes). Review a handful of questions, reflect on the explanations.

3. Learn from the Explanations

After answering a question, always read the explanation, even if you got it right. It reinforces key points, corrects misunderstandings, and teaches subtle distinctions between similar answers.

4. Track Your Progress

Use bookmarks or notes (if reading digitally) to mark difficult questions. Revisit these regularly and track improvements over time.

5. Simulate the Real Exam

Once you're comfortable, try taking a full set of questions without pausing. Set a timer and simulate test-day conditions to build confidence and time management skills.

6. Repeat and Review

Don't just study once, repetition builds retention. Re-attempt questions after a few days and revisit explanations to reinforce learning. Pair this guide with other Examzify tools like flashcards, and digital practice tests to strengthen your preparation across formats.

There's no single right way to study, but consistent, thoughtful effort always wins. Use this guide flexibly, adapt the tips above to fit your pace and learning style. You've got this!

Questions

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- 1. Which is NOT a method to increase efficiency in assuring accuracy and completeness of information?**
 - A. Relying solely on the investigator's memory
 - B. Creating/using standard procedure for abstraction and verification
 - C. Determining quality of source data prior to abstraction
 - D. Increasing efficiency with methods like batching
- 2. What form is used to communicate FDA audit findings?**
 - A. FDA Form 483
 - B. FDA Form 990
 - C. FDA Form 1020
 - D. FDA Audit Report
- 3. What is the general legal age to provide consent in the US?**
 - A. 16
 - B. 18
 - C. 21
 - D. Varies by state
- 4. What must be recorded to maintain adequate IP records?**
 - A. Dosage only
 - B. Side effects only
 - C. Dates, quantities, batch/serial numbers, expiration dates, and codes
 - D. Subject's name and diagnosis only
- 5. How long should sponsors keep study records for device trials?**
 - A. 1 year after the PMA is approved
 - B. 2 years after the investigation is terminated/completed
 - C. 5 years after the product is launched
 - D. 3 years after the last product is shipped
- 6. When can a CRF be considered a source document?**
 - A. When it is submitted to the IRB
 - B. When it is digitalized
 - C. When it is stored in a secure location
 - D. When CRF is signed, dated, and initialed by the person recording the information

- 7. Which of the following is a criterion for Phase 1 protocol as required by the FDA?**
- A. Maximum number of subjects involved
 - B. Color scheme of study material
 - C. List of potential sponsors
 - D. Predicted stock value impact
- 8. What type of evaluations should be documented as attachments to research proposals by IRBs?**
- A. Legal evaluations
 - B. Financial evaluations
 - C. Scientific evaluations
 - D. Ethical evaluations
- 9. Which of the following is NOT a factor statisticians consider to evaluate sample size?**
- A. Blinding method
 - B. Magnitude of IP effect expected between treatment arms
 - C. Variability of outcome
 - D. Probability of observing effect
- 10. How many days does a sponsor have to report withdrawal of FDA approval?**
- A. Immediately
 - B. Within 5 working days
 - C. Within 10 working days
 - D. Within 30 calendar days

Answers

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1. A
2. A
3. B
4. C
5. B
6. D
7. A
8. C
9. A
10. B

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Explanations

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1. Which is NOT a method to increase efficiency in assuring accuracy and completeness of information?

- A. Relying solely on the investigator's memory**
- B. Creating/using standard procedure for abstraction and verification
- C. Determining quality of source data prior to abstraction
- D. Increasing efficiency with methods like batching

Memory can be unreliable and easily influenced by external factors, so relying solely on memory is not a reliable method for ensuring accuracy and completeness of information. Standard procedures for abstraction and verification help to establish a consistent and thorough process that can catch any errors or inconsistencies. Determining the quality of source data allows for identification of potential issues and correction prior to abstraction. Batching is another method that can improve efficiency by organizing and processing information in batches, but it should not be relied on as the sole method for accuracy and completeness.

2. What form is used to communicate FDA audit findings?

- A. FDA Form 483**
- B. FDA Form 990
- C. FDA Form 1020
- D. FDA Audit Report

FDA Form 483 is the most commonly used form to communicate FDA audit findings. It is used to document and communicate any observations and deviations found during an FDA inspection to a company. This form is used by the FDA to inform the company of any potential violations and to request a response from the company on how they plan to address and correct these issues. Option B, FDA Form 990, is a tax document that is used by certain tax-exempt organizations and non-profits to report their financial information to the Internal Revenue Service (IRS). This form has no relation to FDA audit findings. Option C, FDA Form 1020, does not exist. This may have been a distractor choice. Option D, FDA Audit Report, is a generic term that can refer to any report that is generated as a result of an FDA audit. It is not a specific form and is not typically

3. What is the general legal age to provide consent in the US?

- A. 16
- B. 18**
- C. 21
- D. Varies by state

In the US, the general legal age to provide consent is 18. This is the age at which an individual is considered an adult and is therefore legally able to make decisions on their own behalf. Option A, 16, may be the age of consent in some states, but it is not the general legal age in the US. Option C, 21, may be the legal age to purchase alcohol and in some cases to rent a car, but it is not the general legal age for providing consent. Option D, "varies by state", is not completely incorrect, as some states may have different ages of consent. However, the correct and most widely applicable general legal age in the US is 18.

4. What must be recorded to maintain adequate IP records?

- A. Dosage only
- B. Side effects only
- C. Dates, quantities, batch/serial numbers, expiration dates, and codes**
- D. Subject's name and diagnosis only

Recording Dates, quantities, batch/serial numbers, expiration dates, and codes is necessary to maintain adequate IP records because it provides detailed information to track and identify specific medications, doses, and treatments received by a subject. This ensures accurate record-keeping and allows for proper medication management and monitoring. Option A is incorrect because recording dosage only does not provide sufficient information for proper tracking and management. Option B is incorrect because recording side effects only does not capture important details about the medication itself, such as batch and expiration dates, which are important for monitoring and potential recalls. Option D is incorrect because recording only the subject's name and diagnosis does not provide any information about the specific medications and treatments received.

5. How long should sponsors keep study records for device trials?

- A. 1 year after the PMA is approved
- B. 2 years after the investigation is terminated/completed**
- C. 5 years after the product is launched
- D. 3 years after the last product is shipped

Sponsors should keep study records for device trials for at least 2 years after the investigation is terminated or completed. This option ensures that all necessary information is still available for any potential follow-up or audits. Options A, C, and D do not provide a sufficient time frame to maintain study records. Option A may not allow enough time for potential follow-up or audits, as the approval process for a PMA can take several years. Option C only applies to the record-keeping requirements for a launched product, not the duration of a study. Option D only applies to the last product shipped, not the entire duration of the study.

6. When can a CRF be considered a source document?

- A. When it is submitted to the IRB
- B. When it is digitalized
- C. When it is stored in a secure location
- D. When CRF is signed, dated, and initialed by the person recording the information**

A CRF (Case Report Form) is a document used to collect and record data during a clinical trial or patient study. A CRF can be considered a source document when it is the original document that contains the raw data, such as a patient's medical history, lab results, or other study-related information. This means that the data on the CRF is directly obtained from the source, without any alterations or interpretations. Therefore, options A, B, and C are incorrect because they do not relate to the originality of the data on the CRF. Option A refers to the submission of the CRF to the IRB (Institutional Review Board), which is a process that ensures the protection of human subjects in a research study but does not affect the CRF's status as a source document. Option B refers to the digitalization of the CRF, which is simply a

7. Which of the following is a criterion for Phase 1 protocol as required by the FDA?

A. Maximum number of subjects involved

B. Color scheme of study material

C. List of potential sponsors

D. Predicted stock value impact

The criterion for Phase 1 protocol required by the FDA is the maximum number of subjects involved. This is because Phase 1 trials are focused on testing the safety and tolerability of a new drug or treatment in a small group of healthy individuals. Therefore, it is important to limit the number of participants in order to minimize potential risks and gather manageable data. Option B, the color scheme of study material, and option C, the list of potential sponsors, are not relevant criteria for Phase 1 protocols. Option D, the predicted stock value impact, may be a consideration for companies conducting a clinical trial, but it is not a required criterion by the FDA.

8. What type of evaluations should be documented as attachments to research proposals by IRBs?

A. Legal evaluations

B. Financial evaluations

C. Scientific evaluations

D. Ethical evaluations

Scientific evaluations should be documented as attachments to research proposals by IRBs because they provide essential information about the validity and feasibility of the proposed research. Legal evaluations may also be necessary, but they are typically handled by another committee or department. Financial evaluations are important in determining funding and resources for the research, but they do not pertain directly to ethical considerations. Ethical evaluations are the responsibility of the IRB and should not be listed as attachments. Therefore, scientific evaluations are the most relevant and essential type of evaluation to include as an attachment to a research proposal by an IRB.

9. Which of the following is NOT a factor statisticians consider to evaluate sample size?

A. Blinding method

B. Magnitude of IP effect expected between treatment arms

C. Variability of outcome

D. Probability of observing effect

The other options are incorrect because they all pertain to factors that statisticians typically consider when evaluating sample size. Blinding method ensures objectivity and reduces bias, magnitude of IP effect helps determine the appropriate sample size to detect a significant difference, variability of outcome affects the precision of the estimated effect, and probability of observing effect is a crucial factor in determining power and sample size calculations. A blinding method, on the other hand, does not directly impact the sample size calculation and is not a factor that is typically considered in this context. It is used to reduce bias and ensure objectivity in the study design and data collection process.

10. How many days does a sponsor have to report withdrawal of FDA approval?

- A. Immediately
- B. Within 5 working days**
- C. Within 10 working days
- D. Within 30 calendar days

After FDA approval, the sponsor has 5 working days to report any withdrawal of approval. This is the most timely option compared to the other choices. While option A says "immediately," this is too vague and does not specify a specific timeframe. Option C and D mention "working days" and "calendar days" respectively, which can cause confusion as to the exact timeframe allowed for reporting. Therefore, option B is the best choice as it clearly states within 5 working days.

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Next Steps

Congratulations on reaching the final section of this guide. You've taken a meaningful step toward passing your certification exam and advancing your career.

As you continue preparing, remember that consistent practice, review, and self-reflection are key to success. Make time to revisit difficult topics, simulate exam conditions, and track your progress along the way.

If you need help, have suggestions, or want to share feedback, we'd love to hear from you. Reach out to our team at hello@examzify.com.

Or visit your dedicated course page for more study tools and resources:

<https://ccrpsocraexam.examzify.com>

We wish you the very best on your exam journey. You've got this!

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