

# SOCRA CCRP Practice Exam (Sample)

## Study Guide



**Everything you need from our exam experts!**

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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. How are medical devices categorized for regulatory purposes?**
  - A. Class I, II, III**
  - B. By their manufacturer**
  - C. By their usage in medical practice**
  - D. By their price**
  
- 2. Which of the following is not a direct responsibility of an investigator during study visits?**
  - A. Conducting unrelated medical procedures**
  - B. Performing or overseeing trial-related procedures**
  - C. Evaluating subjects' response to treatment**
  - D. Ensuring assessments of adverse events**
  
- 3. What must be documented in IRB meeting minutes regarding actions taken?**
  - A. Only approved actions**
  - B. Only disapproved actions**
  - C. Actions taken by IRB**
  - D. Planned future actions**
  
- 4. What does OAI stand for in FDA inspection classifications?**
  - A. Operational Audit Inquiry**
  - B. Overall Inspection Authority**
  - C. Official Action Indicated**
  - D. Operational Activity Index**
  
- 5. Which of the following is not one of the seven recommendations for electronic document systems?**
  - A. Ensure systems document data changes**
  - B. Allow unrestricted access to data for all employees**
  - C. Maintain security system that prevents unauthorized access**
  - D. Maintain list of individuals authorized to make data changes**

- 6. Investigators must report SAEs to the sponsor within how many days of discovering the event?**
- A. Immediately**
  - B. 5 days**
  - C. 10 days**
  - D. 15 days**
- 7. What should be included in the 'Treatment of Subjects' section of the protocol?**
- A. Screening procedures**
  - B. Details about the administration of the investigational product, including storage and accountability**
  - C. Consent process**
  - D. Data management plan**
- 8. What are historical controls?**
- A. Data from previous trials on the same disease**
  - B. Data from the general population**
  - C. Data from similar patients or the same patient in a crossover study**
  - D. Data from animal studies**
- 9. 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**
- 10. What does ICH stand for in ICH GCP guideline?**
- A. International Council for Harmonisation**
  - B. International Chamber of Health**
  - C. Integrated Clinical Health Group**
  - D. Intercontinental Health and Care Panel**

## Answers

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

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## **Explanations**

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**1. How are medical devices categorized for regulatory purposes?**

**A. Class I, II, III**

**B. By their manufacturer**

**C. By their usage in medical practice**

**D. By their price**

Medical devices are categorized by their risk level and level of regulation needed, which determines which category they fall under, not by their manufacturer, usage in medical practice, or price. Class I medical devices pose the lowest risk and are subject to the least amount of regulation, while Class II and III medical devices pose higher risks and are subject to more regulatory oversight. Therefore, Option A is the correct answer as it correctly identifies the order in which medical devices are categorized based on their risk level and level of regulation needed.

**2. Which of the following is not a direct responsibility of an investigator during study visits?**

**A. Conducting unrelated medical procedures**

**B. Performing or overseeing trial-related procedures**

**C. Evaluating subjects' response to treatment**

**D. Ensuring assessments of adverse events**

An investigator is responsible for conducting and overseeing trial-related procedures, as well as evaluating subjects' response to treatment and ensuring assessments of adverse events. However, conducting unrelated medical procedures is not a direct responsibility of an investigator during study visits. An investigator's focus should be on the specific procedures and assessments related to the study and not on any other medical procedures that may be needed, as those are outside of the scope of the study and the investigator's role.

**3. What must be documented in IRB meeting minutes regarding actions taken?**

**A. Only approved actions**

**B. Only disapproved actions**

**C. Actions taken by IRB**

**D. Planned future actions**

Meeting minutes are important records of an IRB meeting, and they should accurately reflect the actions taken during the meeting. This includes not only approved actions, but also any disapproved actions and any actions taken by the IRB. Therefore, options A and B are incorrect because they make assumptions that only certain types of actions should be included in the meeting minutes. Option D is also incorrect because the focus should be on actions that were already taken during the meeting, not on future actions that are yet to be determined. This means that the most comprehensive and accurate choice is option C. It is important to document all actions taken during an IRB meeting in order to provide a complete and transparent record of the meeting.

**4. What does OAI stand for in FDA inspection classifications?**

- A. Operational Audit Inquiry**
- B. Overall Inspection Authority**
- C. Official Action Indicated**
- D. Operational Activity Index**

OAI stands for Official Action Indicated. This refers to a classification used by the FDA when there is evidence of significant violation of regulatory standards during an inspection. Options A, B, and D are incorrect as they do not accurately represent the meaning of OAI in FDA inspection classifications.

**5. Which of the following is not one of the seven recommendations for electronic document systems?**

- A. Ensure systems document data changes**
- B. Allow unrestricted access to data for all employees**
- C. Maintain security system that prevents unauthorized access**
- D. Maintain list of individuals authorized to make data changes**

The seven recommendations for electronic document systems include ensuring systems document data changes, maintaining a security system that prevents unauthorized access, and maintaining a list of individuals authorized to make data changes. Option B, which suggests allowing unrestricted access to data for all employees, goes against the recommendation for maintaining a secure system and controlling access to data. It can potentially compromise the integrity and security of the system and its data. Therefore, it is not considered as one of the seven recommendations.

**6. Investigators must report SAEs to the sponsor within how many days of discovering the event?**

- A. Immediately**
- B. 5 days**
- C. 10 days**
- D. 15 days**

SAEs (Serious Adverse Events) must be reported to the sponsor immediately upon discovery because timely reporting is crucial in ensuring the safety and well-being of participants in a clinical trial. Waiting even 5, 10, or 15 days may result in potential harm to participants or delay in taking necessary actions. Therefore, the other options are incorrect because they suggest a longer time frame, which could be detrimental to the safety of the participants. Reporting SAEs immediately also allows the sponsor to act quickly and appropriately, potentially preventing any further incidents.

**7. What should be included in the 'Treatment of Subjects' section of the protocol?**

- A. Screening procedures
- B. Details about the administration of the investigational product, including storage and accountability**
- C. Consent process
- D. Data management plan

The 'Treatment of Subjects' section of the protocol should include details about the administration of the investigational product, including storage and accountability. This section should not include details about screening procedures (A) as those should be outlined in the 'Selection of Subjects' section. The consent process (C) should be discussed in the 'Informed Consent' section of the protocol. The data management plan (D) should be included in the 'Data Collection and Management' section. It is important to include specific and detailed information about the investigational product in the 'Treatment of Subjects' section to ensure that the subjects are properly and consistently treated during the study.

**8. What are historical controls?**

- A. Data from previous trials on the same disease
- B. Data from the general population
- C. Data from similar patients or the same patient in a crossover study**
- D. Data from animal studies

Historical controls refer to data from similar patients in a study or the same patient in a crossover study, while options A, B, and D refer to data from different sources that may not be as relevant or applicable to the current study. Option A specifically refers to data from previous trials on the same disease, which may have different variables and outcomes, making it difficult to compare to the current study. Option B refers to data from the general population, which may not accurately represent the specific population being studied. Option D refers to data from animal studies, which may not always translate to human results. Therefore, option C is the most accurate and relevant answer for historical controls in a study.

**9. 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.

**10. What does ICH stand for in ICH GCP guideline?**

**A. International Council for Harmonisation**

**B. International Chamber of Health**

**C. Integrated Clinical Health Group**

**D. Intercontinental Health and Care Panel**

ICH stands for International Council for Harmonisation, which is a global organization that brings together experts from pharmaceutical regulatory agencies and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product registration. Therefore, options B, C, and D are incorrect as they do not accurately represent the purpose or name of the organization. The correct answer, A, clearly denotes the correct acronym and organization that is referenced in the question.

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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](mailto: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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