

ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS (ACRP) CERTIFIED PROFESSIONAL PRACTICE EXAM (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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THE FULL VERSION STUDY GUIDE

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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. What is the function of a Legally Acceptable Representative (LAR) in research?**
 - A. To offer financial sponsorship
 - B. To approve research funding
 - C. To consent on behalf of participants
 - D. To oversee clinical trials
- 2. What is required for a serious adverse event (SAE) to be reported to authorities?**
 - A. Any occurrence that requires outpatient care
 - B. An occurrence that results in significant disability or death
 - C. Any unexpected reaction to a drug
 - D. Limited to experiences only reported by the investigator
- 3. What is the aim of a Therapeutic Trial?**
 - A. To analyze the pricing strategy of a new drug
 - B. To study the specific treatment's impact on cancer
 - C. To collect preliminary data on market trends
 - D. To understand patient perceptions of treatment
- 4. A study focusing on determining the ideal dose of a new investigational product for treating hypothyroidism is classified as which phase?**
 - A. Phase I
 - B. Phase II
 - C. Phase III
 - D. Phase IV
- 5. Which element is essential to include in a clinical trial protocol?**
 - A. Study funding sources
 - B. Subject inclusion and exclusion criteria
 - C. Statistical analysis plan
 - D. Institutional affiliations

- 6. True or False: An IRB/IEC may request additional information if it is deemed to enhance subject protection.**
- A. True
 - B. False
 - C. Depends on the clinical trial
 - D. True only if requested by sponsors
- 7. Which document provides prior clinical and nonclinical results of investigational products (IP) to the investigator?**
- A. Clinical trial agreement
 - B. Investigator's brochure
 - C. Study protocol
 - D. Ethics committee report
- 8. What phase of clinical research involves dose-tolerance, single/multiple dose PK, and drug interaction studies?**
- A. Phase 1
 - B. Phase 2
 - C. Phase 3
 - D. Phase 4
- 9. Before archiving a study, where should documentation of investigational product (IP) destruction be filed?**
- A. In the sponsor's central files
 - B. In the study files of the PI and Sponsor
 - C. In the FDA submission package
 - D. In the subject's medical records
- 10. Which age group is particularly marked by issues of non-compliance in clinical trials?**
- A. Children
 - B. Infants
 - C. Adolescents
 - D. Adults

Answers

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

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Explanations

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1. What is the function of a Legally Acceptable Representative (LAR) in research?

- A. To offer financial sponsorship
- B. To approve research funding
- C. To consent on behalf of participants**
- D. To oversee clinical trials

The function of a Legally Acceptable Representative (LAR) in research is to consent on behalf of participants who are unable to provide informed consent themselves. This typically applies to individuals who may not have the capacity to understand the information necessary to make an informed decision about their participation in a research study, such as minors or individuals with cognitive impairments. The LAR is legally authorized to make decisions regarding participation in research, ensuring that the rights and welfare of the potential participant are protected. In research ethics, obtaining informed consent is a crucial step, ensuring that participants understand the nature of the study, its risks, and benefits. However, situations arise where individuals cannot provide that consent, making the role of the LAR vital in upholding the ethical standards of research. This representative must be someone who is familiar with the participant's situation and interests, typically a family member or legal guardian, ensuring that the consent process remains aligned with the participant's values and preferences.

2. What is required for a serious adverse event (SAE) to be reported to authorities?

- A. Any occurrence that requires outpatient care
- B. An occurrence that results in significant disability or death**
- C. Any unexpected reaction to a drug
- D. Limited to experiences only reported by the investigator

For a serious adverse event (SAE) to be reported to authorities, it must result in significant disability or death. This definition focuses on the severity of the event and its impact on the patient's health status. Serious adverse events are critical in clinical research and pharmacovigilance because they can indicate potential risks associated with a medical product or intervention that must be closely monitored. Reporting SAEs is essential for ensuring participant safety, as these events can have serious implications for patient care and public health. Events leading to significant disability highlight a change in the patient's functional abilities or overall quality of life, while those resulting in death represent the most severe outcome, necessitating immediate attention from regulatory authorities. In contrast, other options do not capture the important severity or impact required for an SAE. For instance, occurrences that require outpatient care may not necessarily indicate a serious event. Similarly, while unexpected reactions to a drug can be concerning, they do not meet the threshold of seriousness without leading to significant disability or death. Lastly, limiting reports to experiences shared solely by the investigator does not align with the rigorous requirements and responsibilities placed on all stakeholders in a clinical study to ensure participant safety.

3. What is the aim of a Therapeutic Trial?

- A. To analyze the pricing strategy of a new drug
- B. To study the specific treatment's impact on cancer**
- C. To collect preliminary data on market trends
- D. To understand patient perceptions of treatment

Therapeutic trials are meant to test whether a specific treatment has a real clinical effect on the disease in patients. In cancer, this means giving the treatment to people with cancer and carefully measuring outcomes that show benefit and safety—such as tumor response, delay of progression, improved survival, or better quality of life—while tracking adverse effects. The purpose is to determine if the intervention provides meaningful clinical benefit and warrants further study or use, rather than exploring business aspects like pricing, market trends, or patient opinions, which fall outside the trial's scientific goals.

4. A study focusing on determining the ideal dose of a new investigational product for treating hypothyroidism is classified as which phase?

- A. Phase I
- B. Phase II**
- C. Phase III
- D. Phase IV

The correct classification for a study aiming to determine the ideal dose of a new investigational product for treating hypothyroidism is Phase II. This phase is primarily concerned with evaluating the efficacy of the medication, along with dosing requirements, after initial safety has been established in Phase I trials. In Phase II, researchers often focus on different dose levels to find the most effective and safe dosage to treat the condition, which aligns with the objectives of the study described in the question. During Phase I, the focus is mainly on assessing safety and tolerability, often with small groups of healthy participants rather than those with the targeted condition. Therefore, the determination of the ideal dose, relevant to the effectiveness of the drug in patients suffering from hypothyroidism, positions the study firmly within Phase II. Phase III would involve larger trials that further evaluate effectiveness, monitor side effects, and compare the drug to commonly used treatments, while Phase IV studies occur after a drug has been marketed, focusing on long-term effectiveness and safety in diverse populations.

5. Which element is essential to include in a clinical trial protocol?

- A. Study funding sources
- B. Subject inclusion and exclusion criteria**
- C. Statistical analysis plan
- D. Institutional affiliations

Including subject inclusion and exclusion criteria in a clinical trial protocol is crucial because these criteria dictate the specific characteristics of individuals who can participate in the study. These criteria guide the selection of a participant population that is appropriate for the research objectives and the safety of both participants and the integrity of the data collected. Clearly defined criteria ensure that the trial meets ethical standards and regulatory requirements, as they help identify individuals who are most likely to benefit from the intervention and minimize risks associated with participation. Additionally, well-defined inclusion and exclusion criteria contribute to the study's validity by preventing confounding variables that could affect the outcomes. While other elements, such as study funding sources, statistical analysis plans, and institutional affiliations, are important components of a clinical trial protocol, the inclusion and exclusion criteria are fundamental to participant recruitment and the overall design of the trial. This is essential for ensuring that the results are applicable to the intended patient population and that the study rigorously tests the hypothesis it aims to evaluate.

6. True or False: An IRB/IEC may request additional information if it is deemed to enhance subject protection.

A. True

B. False

C. Depends on the clinical trial

D. True only if requested by sponsors

An IRB (Institutional Review Board) or IEC (Independent Ethics Committee) plays a crucial role in overseeing the ethical aspects of clinical trials and research involving human subjects. One of their primary responsibilities is to ensure that the rights, safety, and well-being of the participants are protected throughout the study. When an IRB/IEC reviews a study protocol, they may identify gaps or areas where additional information could enhance the understanding of potential risks or improve the proposed protections for subjects. In such cases, the board may request further information from the researchers to address these concerns. This additional information could include clarification on study procedures, risk management strategies, or monitoring practices. The ability of an IRB/IEC to request additional data underscores their commitment to ethical oversight and highlights the iterative nature of the review process. It ensures that the research conforms to ethical standards, aligns with regulatory requirements, and considers the welfare of participants as paramount. Thus, it is valid to assert that they have the authority to request additional information aimed at enhancing subject protection, which is why the statement is true.

7. Which document provides prior clinical and nonclinical results of investigational products (IP) to the investigator?

A. Clinical trial agreement

B. Investigator's brochure

C. Study protocol

D. Ethics committee report

The Investigator's Brochure is a comprehensive document that provides critical information about an investigational product (IP). It is designed to inform the investigator and healthcare professionals involved in the clinical trial about the prior clinical and nonclinical results associated with the IP. This document contains essential data such as pharmacology, toxicology, and previous study outcomes that could affect the safety and efficacy evaluation of the product. The information presented in the Investigator's Brochure is crucial for enabling investigators to understand the background of the investigational product, assess the risk-benefit profile, and make informed decisions regarding participant safety and dosage during the trial. This foundation of knowledge is essential for the ethical conduct of clinical research, ensuring that investigators are well-equipped with relevant background information before participating in a study. In contrast, other options like the Clinical Trial Agreement relate more to the legal and operational aspects of conducting a trial, while the Study Protocol outlines the design and methodology of the study without providing prior results. An Ethics Committee Report typically focuses on the ethical considerations of a specific study rather than on providing historical data about the investigational product itself.

8. What phase of clinical research involves dose-tolerance, single/multiple dose PK, and drug interaction studies?

- A. Phase 1**
- B. Phase 2
- C. Phase 3
- D. Phase 4

Phase 1 of clinical research is primarily focused on assessing safety, tolerability, and pharmacokinetics (PK) of a drug in humans. During this phase, researchers conduct studies to determine the optimal dosage range and how the drug behaves in the body, including absorption, distribution, metabolism, and excretion. Dose-tolerance studies are essential at this stage, as they help identify the maximum tolerated dose, which is crucial for ensuring patient safety in subsequent phases. Single and multiple dose pharmacokinetic studies are conducted to understand how the drug concentration varies in the bloodstream over time after administration, providing insights into the drug's dosing regimen. Additionally, drug interaction studies during Phase 1 can reveal how the investigational drug might interact with other medications, helping to establish safe administration practices and predict potential adverse effects when combined with commonly used therapies. This focus on establishing initial safety and proper dosing forms the foundation for later phases of clinical research, where the emphasis shifts to effectiveness and broader patient populations.

9. Before archiving a study, where should documentation of investigational product (IP) destruction be filed?

- A. In the sponsor's central files
- B. In the study files of the PI and Sponsor**
- C. In the FDA submission package
- D. In the subject's medical records

Filing documentation of investigational product (IP) destruction in the study files of both the Principal Investigator (PI) and the Sponsor is essential for maintaining an accurate and comprehensive record of the study. This documentation serves as a critical component of the overall study archive, providing evidence that the investigational products were handled and disposed of according to protocol and regulatory guidelines. Having this information readily accessible in the study files ensures that both the PI and Sponsor can refer to it during audits, inspections, or other inquiries regarding the study's conduct. It helps in maintaining accountability and transparency throughout the research process. This aligns with good clinical practice as it supports the integrity of study data and adherence to ethical standards in research. In contrast, while filing this documentation in the sponsor's central files, the FDA submission package, or the subject's medical records may appear important, these options do not provide the same level of direct accessibility and relevance to the specific study's conduct and oversight as the combined study files of the PI and Sponsor do.

10. Which age group is particularly marked by issues of non-compliance in clinical trials?

- A. Children
- B. Infants
- C. Adolescents**
- D. Adults

The age group particularly marked by issues of non-compliance in clinical trials is adolescents. This is primarily due to several psychological and social factors that influence their behavior during the trial process. Adolescents often exhibit a desire for independence and may struggle with authority, which can lead to a lack of adherence to study protocols. Additionally, issues related to impulsivity and peer influence can further complicate their commitment to following the guidelines set forth in trials. Moreover, this age group may experience challenges in understanding the importance of compliance, leading to a higher likelihood of missed doses, failure to attend follow-up visits, or misunderstandings about the study requirements. The development stage of adolescents can also make them less likely to prioritize health-related activities, which can hinder their participation in clinical trials. In contrast, compliance issues are typically not as pronounced in other age groups such as children or infants, where caregivers play a significant role in managing participation and adherence to protocols. Adults may also face compliance challenges, but generally have more life experience and understanding of the importance of following study guidelines compared to adolescents.

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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://acrp-cp.examzify.com>

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

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