

Association of Clinical Research Professionals (ACRP) Certified Professional 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

- 1. When initiating a study for a new combination of drugs, what committee is typically established for oversight?**
 - A. Research Ethics Committee**
 - B. Independent Data Monitoring Committee**
 - C. Institutional Review Board**
 - D. Safety Monitoring Board**
- 2. Which statement concerning trial phases is true?**
 - A. All phases assess efficacy in patients**
 - B. Phase I trials are most typical for large populations**
 - C. Initial administration of a drug occurs in Phase I**
 - D. Phase III is only concerned with toxicity**
- 3. Who is responsible for sending Annual Progress Reports to the IRB/IEC?**
 - A. The Sponsor**
 - B. The Investigator**
 - C. The Clinical Research Coordinator**
 - D. The Principal Investigator**
- 4. Is the investigator required to share the names of subjects with the IRB/IEC?**
 - A. Yes**
 - B. No**
 - C. Only under certain circumstances**
 - D. It depends on the protocol**
- 5. In clinical research, which term is used to describe the potential beneficial effects of a new treatment?**
 - A. Pharmacodynamics**
 - B. Therapeutic efficacy**
 - C. Tolerability**
 - D. Sustainability**

- 6. What does a wider Confidence Interval (CI) indicate about data variability?**
- A. Less variability**
 - B. No variability**
 - C. More variability**
 - D. Stable data**
- 7. According to regulations, how long should essential documents be retained after the last marketing application approval?**
- A. 1 year**
 - B. 2 years**
 - C. 3 years**
 - D. 5 years**
- 8. Who is qualified to administer a psychometric test in a study of cognitive impairment?**
- A. A licensed psychologist**
 - B. A research assistant who is certified to administer the psychometric test**
 - C. The principal investigator**
 - D. A graduate-level intern in psychology**
- 9. What is the main function of the Data and Safety Monitoring Board (DSMB)?**
- A. To analyze financial costs of the trial.**
 - B. To assess trial progress and recommend modifications, terminations, or continuations.**
 - C. To recruit participants for future trials.**
 - D. To conduct training for clinical trial staff.**
- 10. Which organization establishes standards related to the inclusion of special populations in clinical research?**
- A. FDA**
 - B. WHO**
 - C. ICH**
 - D. NIH**

Answers

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

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Explanations

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1. When initiating a study for a new combination of drugs, what committee is typically established for oversight?

- A. Research Ethics Committee**
- B. Independent Data Monitoring Committee**
- C. Institutional Review Board**
- D. Safety Monitoring Board**

The establishment of an Independent Data Monitoring Committee (IDMC) is essential in overseeing studies involving new combinations of drugs, particularly when safety and efficacy concerns arise during clinical trials. The primary role of the IDMC is to assess accumulating data and ensure the trial is conducted ethically and safely. They monitor interim results to make decisions about the continuation, modification, or termination of the trial based on safety and efficacy. This oversight becomes vital when handling new drug combinations, as the safety profile can be unpredictable, and the committee has the authority to safeguard participant welfare and ensure the integrity of the study. While other committees like the Institutional Review Board (IRB) and Research Ethics Committee are important for ethical oversight and approving study protocols, the IDMC is specifically focused on real-time data analysis throughout the trial, which is crucial for drug combination studies where adverse effects or unexpected outcomes may be more pronounced. The Safety Monitoring Board operates similarly to an IDMC, but the specific distinction here leans towards the independent oversight role of the IDMC in the context of drug combination studies.

2. Which statement concerning trial phases is true?

- A. All phases assess efficacy in patients**
- B. Phase I trials are most typical for large populations**
- C. Initial administration of a drug occurs in Phase I**
- D. Phase III is only concerned with toxicity**

The correct answer highlights that the initial administration of a new drug to human participants occurs during Phase I trials. Phase I trials are primarily designed to evaluate the safety, tolerability, and pharmacokinetics of a drug in a small group of participants, typically ranging from 20 to 100 healthy volunteers or patients. The primary focus at this stage is to determine how the drug behaves in the body and identify any potential side effects, thereby laying the groundwork for subsequent dosing in later phases. Understanding this context is important because while all phases of clinical trials play a role in assessing various aspects of a drug's effect, the initial exposure to the drug specifically happens during Phase I. This phase serves as a crucial step before further investigating the drug's efficacy and safety in larger populations in subsequent phases.

3. Who is responsible for sending Annual Progress Reports to the IRB/IEC?

- A. The Sponsor**
- B. The Investigator**
- C. The Clinical Research Coordinator**
- D. The Principal Investigator**

The responsibility for sending Annual Progress Reports to the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) primarily lies with the Investigator. This can often be the Principal Investigator, who leads the clinical trial, but it is typically framed within the broader role of the Investigator in the context of regulatory compliance and ethical oversight. The Annual Progress Report is an essential component of the ongoing communication between the study site and the IRB/IEC, helping to ensure that the study continues to align with ethical standards and regulatory requirements. This report provides important updates on the trial's status, enrollment figures, any adverse events that may have occurred, and updates on protocol deviations. The Investigator, having the most direct interactions with the trial's operations, is ideally positioned to provide accurate and comprehensive updates. While the Sponsor, Clinical Research Coordinator, and Principal Investigator have significant roles within the study, the responsibility for communication regarding the ongoing status and ethical conduct of the study primarily rests with the Investigator.

4. Is the investigator required to share the names of subjects with the IRB/IEC?

- A. Yes**
- B. No**
- C. Only under certain circumstances**
- D. It depends on the protocol**

The correct answer indicates that the investigator is not required to share the names of subjects with the Institutional Review Board (IRB) or Independent Ethics Committee (IEC). This is primarily due to the principles of confidentiality and the ethical treatment of research subjects. Protecting the privacy of research participants is a fundamental aspect of research ethics, and disclosing their identities to the IRB/IEC is generally unnecessary for the review of the research protocol. IRBs/IECs are tasked with evaluating the ethical aspects of research studies, including risks and benefits, informed consent processes, and the adequacy of privacy protections. They are equipped to assess these factors without needing to know the identities of the participants involved. Instead, investigators typically provide aggregated data or summaries that allow the IRB/IEC to perform their duties while maintaining the confidentiality of individual subjects. Sharing personal identifying information could potentially lead to privacy violations and might discourage individuals from participating in research studies, which could impede scientific progress. Therefore, maintaining anonymity is fundamental in protecting participants' rights and encouraging ethical compliance.

5. In clinical research, which term is used to describe the potential beneficial effects of a new treatment?

- A. Pharmacodynamics**
- B. Therapeutic efficacy**
- C. Tolerability**
- D. Sustainability**

The term that describes the potential beneficial effects of a new treatment is therapeutic efficacy. This concept refers to the effectiveness of a treatment or intervention in producing a desired clinical outcome in patients under ideal and controlled circumstances. Assessing therapeutic efficacy is a critical component of clinical trials, as researchers aim to establish how well a treatment works compared to a placebo or standard treatment. To evaluate therapeutic efficacy, clinical trials typically measure outcomes such as symptom improvement, disease progression, or overall survival rates, depending on the condition being treated. The findings inform healthcare providers and patients about the likely benefits of a new therapeutic option, guiding clinical decisions and advancing treatment protocols. The other terms listed do not specifically define the beneficial effects of a treatment. Pharmacodynamics refers to the study of how a drug affects an organism, which encompasses aspects like the mechanism of action and dose-response relationships but does not singularly focus on benefits. Tolerability relates to the extent to which adverse effects of a drug can be tolerated by patients, while sustainability typically pertains to long-term effects and maintenance of outcomes rather than immediate therapeutic benefits.

6. What does a wider Confidence Interval (CI) indicate about data variability?

- A. Less variability**
- B. No variability**
- C. More variability**
- D. Stable data**

A wider Confidence Interval (CI) indicates more variability in the data. The Confidence Interval represents the range of values within which we can expect the true population parameter to lie, with a specified level of confidence (commonly 95%). When the CI is wide, it signifies that there is greater uncertainty about the estimate of the parameter, reflecting a larger spread of the data points. This could be due to high variability within the data collected, insufficient sample size, or both. As the variability in the data increases, the range of values that could represent the true parameter also increases, resulting in a wider CI. Thus, a wider CI is an important consideration in statistical analysis, as it can provide insights into the reliability and precision of the estimates derived from the sample data.

7. According to regulations, how long should essential documents be retained after the last marketing application approval?

- A. 1 year
- B. 2 years**
- C. 3 years
- D. 5 years

The correct retention period for essential documents after the last marketing application approval is two years. This requirement is established to ensure that all relevant records and documents are maintained long enough to support any necessary audits, regulatory inspections, or reviews that may occur in relation to the authorized marketing application. This retention period aligns with the industry standards that specify that documents must remain accessible for a duration sufficient to address any potential inquiries or requirements that arise from regulatory bodies or stakeholders involved in the process. In the context of clinical trials and drug development, maintaining such records signifies an organization's commitment to compliance and transparency. Retaining documents for a set period also aligns with regulatory good practices, allowing for adequate assessments of safety and efficacy based on past studies, should any questions arise post-approval. In summary, the two-year retention period is essential for upholding regulatory and legal standards and ensuring that all documentation is readily available for future reference, thereby supporting ongoing patient safety and effective drug monitoring.

8. Who is qualified to administer a psychometric test in a study of cognitive impairment?

- A. A licensed psychologist
- B. A research assistant who is certified to administer the psychometric test**
- C. The principal investigator
- D. A graduate-level intern in psychology

The qualification to administer a psychometric test in a study of cognitive impairment typically hinges on the certification specific to that test. A research assistant who is certified to administer the psychometric test signifies that they have received the necessary training and have demonstrated the competence to properly conduct the assessment and interpret the results in accordance with established guidelines. This certification ensures that the individual understands how to administer the test accurately and ethically, as well as how to accommodate the needs of participants, which is crucial in studies involving cognitive functioning. Certification also often entails familiarity with ethical considerations and the ability to handle sensitive information, further validating their capability in a research setting. While a licensed psychologist and principal investigators generally possess a high level of expertise in psychological assessments, they may not always be the ones administering every test, especially in larger studies where multiple tasks are delegated. Similarly, a graduate-level intern may be knowledgeable but may lack the specific certification necessary for certain psychometric tests. Thus, the presence of certification in the context of the research underscores the importance of adhering to protocols and standards in psychological testing.

9. What is the main function of the Data and Safety Monitoring Board (DSMB)?

- A. To analyze financial costs of the trial.
- B. To assess trial progress and recommend modifications, terminations, or continuations.**
- C. To recruit participants for future trials.
- D. To conduct training for clinical trial staff.

The primary function of the Data and Safety Monitoring Board (DSMB) is to oversee the progress of a clinical trial, ensuring the safety of the participants and the integrity of the data being collected. This board is tasked with ongoing reviews of the trial's data, looking for any safety issues or concerning trends that may emerge as the trial progresses. They have the authority to recommend changes to the trial protocol, halt the study if necessary due to safety concerns, or suggest that it continues as planned based on the assessment of the emerging data. This oversight is crucial because it helps protect participants from potential harm and ensures that the clinical trial adheres to ethical and safety standards. By making recommendations regarding modifications, terminations, or continuations of the trial based on their assessments, the DSMB plays a critical role in the development and approval process of new treatments and interventions.

10. Which organization establishes standards related to the inclusion of special populations in clinical research?

- A. FDA
- B. WHO
- C. ICH**
- D. NIH

The correct organization that establishes standards related to the inclusion of special populations in clinical research is the International Council for Harmonisation (ICH). The ICH plays a critical role in developing guidelines that aim to ensure that clinical research is conducted ethically and that vulnerable or special populations, such as children, pregnant women, and the elderly, are appropriately included in clinical studies. The guidelines set forth by ICH help ensure that researchers consider the unique needs and circumstances of these populations, promoting safety and efficacy in treatments. In contrast, the FDA (Food and Drug Administration) primarily focuses on the regulation of products to ensure public safety rather than establishing specific standards related to the inclusion of populations in research. The WHO (World Health Organization) addresses global health practices and policy but is less focused on the specifics of clinical research methodologies. The NIH (National Institutes of Health) does promote inclusive research practices; however, it is not the primary organization responsible for developing the international guidelines adopted by clinical researchers around the world, which is the domain of the ICH.

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!