

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. What action must an investigator take upon discovering new safety information about an investigational product?**
 - A. Notify the funding agency**
 - B. Submit a revised Informed Consent Form to the IRB/IEC**
 - C. Inform all subjects immediately**
 - D. Cease the trial immediately**
- 2. What type of study design is most likely used if a sponsor has a new product that is believed to be as effective as an existing treatment?**
 - A. Equivalence**
 - B. Superiority**
 - C. Non-Inferiority**
 - D. Exploratory**
- 3. What qualifies as an Adverse Drug Reaction according to health care professionals or sponsors?**
 - A. Any reaction reported**
 - B. Those with a reasonable suspected causal relationship to the medicinal product**
 - C. Only severe reactions**
 - D. Reactions occurring after trial completion**
- 4. What is a primary function of the Data and Safety Monitoring Board (DSMB)?**
 - A. To enforce clinical trial participants' rights**
 - B. To evaluate trial progress and safety data**
 - C. To approve the study protocol**
 - D. To manage trial funding**
- 5. According to ICH guidelines, how long must an IRB retain correspondence after trial completion?**
 - A. 1 Year**
 - B. 2 Years**
 - C. 3 Years**
 - D. 5 Years**

- 6. An Adverse Event (AE) that is severe in intensity may not meet which definition?**
- A. Serious**
 - B. Expected**
 - C. Related**
 - D. Unrelated**
- 7. What is a key aspect of the Declaration of Helsinki developed by the WMA?**
- A. Regulation of medical device trials**
 - B. Ethical principles for research involving human subjects**
 - C. Funding requirements for clinical research**
 - D. Guidelines for animal testing**
- 8. What is the purpose of masking in clinical trials?**
- A. To improve data collection**
 - B. To ensure unbiased assessment of outcomes**
 - C. To reduce the sample size**
 - D. To determine the study's primary variable**
- 9. What type of trial gathers data without a pre-stated hypothesis?**
- A. Exploratory Trial**
 - B. Confirmatory Trial**
 - C. Therapeutic Trial**
 - D. Pharmacokinetic Trial**
- 10. Can CRAs (monitors) review source documents of subjects who have withdrawn consent?**
- A. Yes, they can review past documents**
 - B. No, they cannot review any documents**
 - C. Only if authorized by the investigator**
 - D. Only if the documents are de-identified**

Answers

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

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Explanations

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1. What action must an investigator take upon discovering new safety information about an investigational product?

A. Notify the funding agency

B. Submit a revised Informed Consent Form to the IRB/IEC

C. Inform all subjects immediately

D. Cease the trial immediately

When an investigator discovers new safety information about an investigational product, it is essential to submit a revised Informed Consent Form to the Institutional Review Board (IRB) or Independent Ethics Committee (IEC). The informed consent process is critical in clinical research as it ensures that participants are fully aware of the potential risks and benefits associated with their involvement in the study. Updating the Informed Consent Form provides participants with the most current information regarding the safety profile of the investigational product. It empowers them to make informed decisions about their continued participation in the study based on the new findings. The IRB/IEC plays a crucial role in reviewing and approving any changes to the informed consent process to ensure that safeguards are in place for participants. While other actions, such as notifying the funding agency or informing subjects, may also be necessary depending on the context of the findings and regulatory requirements, the priority must be given to ensuring that the informed consent reflects the latest safety information. This helps to uphold ethical standards and supports participant autonomy in the research process.

2. What type of study design is most likely used if a sponsor has a new product that is believed to be as effective as an existing treatment?

A. Equivalence

B. Superiority

C. Non-Inferiority

D. Exploratory

The most likely study design used when a sponsor has a new product believed to be as effective as an existing treatment is non-inferiority. This type of study is specifically designed to determine whether the new treatment is not significantly worse than the existing treatment, within a predefined margin. Non-inferiority trials are conducted to demonstrate that the new treatment can offer equivalent benefits, thereby providing evidence that it holds its own against the standard treatment. In this context, the focus is on proving that the new product's effectiveness is not inferior to that of the existing treatment, which aligns seamlessly with the goal of the sponsor who believes in the new product's equivalence. This study design is widely used in clinical research, particularly when the aim is to show that a new drug or therapy can be considered a viable alternative while potentially offering additional benefits such as improved side effect profiles or ease of administration. This approach contrasts with superiority trials, which specifically aim to demonstrate that one treatment is better than another, and equivalence studies, which are designed to show that two treatments are essentially the same. Exploratory studies, on the other hand, are more focused on generating hypotheses rather than confirming specific differences in effectiveness.

3. What qualifies as an Adverse Drug Reaction according to health care professionals or sponsors?

A. Any reaction reported

B. Those with a reasonable suspected causal relationship to the medicinal product

C. Only severe reactions

D. Reactions occurring after trial completion

An Adverse Drug Reaction (ADR) is specifically defined as any unintended and harmful response to a medicinal product for which there is a reasonable suspected causal relationship. This definition emphasizes the importance of establishing a connection between the reaction and the drug in question. When health care professionals or sponsors assess ADRs, they look for evidence that supports the likelihood that the drug may have contributed to the negative outcome. This distinction is crucial because not every reaction reported constitutes an ADR. For instance, simply having a reaction does not indicate that it was caused by the drug; it must not only be reported but also have a plausible link to the drug for it to be classified as an adverse reaction. Thus, the phrasing of the correct answer highlights the necessity of suspecting a causal relationship, which reinforces the need for thorough investigation of each reported reaction. Reactions that are only severe or those occurring after the completion of a trial may not meet the criteria for classification as ADRs, as they do not necessarily account for the required causal relationship to the medicinal product. Similarly, categorizing any reported reaction as an ADR would dilute the significance of such classifications, making it important for health care professionals and sponsors to apply the appropriate criteria.

4. What is a primary function of the Data and Safety Monitoring Board (DSMB)?

A. To enforce clinical trial participants' rights

B. To evaluate trial progress and safety data

C. To approve the study protocol

D. To manage trial funding

The primary function of the Data and Safety Monitoring Board (DSMB) is to evaluate trial progress and safety data. The DSMB serves an important role in overseeing the conduct of clinical trials to ensure the safety of participants and the integrity of the data collected. This independent group monitors trial outcomes, including adverse events and overall effectiveness, to determine whether the trial should continue as planned, be modified, or be halted entirely due to safety concerns or lack of efficacy. This focus on ongoing evaluation helps ensure that any potential risks to participants are promptly addressed and can lead to necessary adjustments in the study design or protocols. While enforcing participants' rights, approving study protocols, and managing trial funding are important aspects of clinical research, they are not the primary responsibilities of the DSMB, which is centered primarily on oversight and monitoring for safety and data integrity.

5. According to ICH guidelines, how long must an IRB retain correspondence after trial completion?

- A. 1 Year**
- B. 2 Years**
- C. 3 Years**
- D. 5 Years**

The correct answer is based on the guidelines provided by the International Council for Harmonisation (ICH) which state that an Institutional Review Board (IRB) must retain correspondence related to clinical trials for a minimum of three years after the completion of the trial. This retention period is set to ensure that there is a comprehensive record of the trial's compliance with ethical standards and regulatory requirements, allowing for adequate oversight and accountability. Retaining correspondence for three years allows the IRB to address any issues that may arise post-trial, such as inquiries into how the trial was conducted or concerns about participant safety and ethics. This timeframe aligns with the need for transparency and thoroughness in clinical research, enabling effective monitoring even after the trial has officially concluded. In contrast, other timeframes such as one year, two years, or five years do not meet the specific requirements outlined by ICH guidelines, which explicitly mandate the three-year retention period.

6. An Adverse Event (AE) that is severe in intensity may not meet which definition?

- A. Serious**
- B. Expected**
- C. Related**
- D. Unrelated**

An adverse event (AE) that is severe in intensity may not meet the definition of "serious" because the term "serious" is specifically linked to outcomes that result in significant medical consequences. While an AE can be classified as severe based on its intensity, it does not automatically indicate that it is serious unless it meets specific criteria, such as resulting in death, being life-threatening, requiring hospitalization, or causing lasting disability. In clinical trials and medical research, the classification of AEs is crucial, and understanding the distinction between severity and seriousness helps in accurately reporting and assessing risks associated with treatments. Severity pertains to the intensity of the AE — for instance, an AE could be rated as severe pain without being serious if it does not lead to serious outcomes. This distinction is vital for ensuring proper patient care and regulatory compliance. The definitions of the other terms, such as "expected," "related," and "unrelated," focus on the relationship of the AE to the treatment or the anticipated outcomes based on prior knowledge, rather than the intensity or seriousness of the event itself. Therefore, while an adverse event may be severe, it might not fulfill the criteria to be classified as serious, hence making this option the correct choice in the question.

7. What is a key aspect of the Declaration of Helsinki developed by the WMA?

- A. Regulation of medical device trials**
- B. Ethical principles for research involving human subjects**
- C. Funding requirements for clinical research**
- D. Guidelines for animal testing**

The Declaration of Helsinki, developed by the World Medical Association (WMA), is primarily focused on establishing ethical principles for research involving human subjects. It provides a foundational framework for ensuring that research is conducted in a manner that respects the rights, safety, and well-being of participants. The declaration emphasizes informed consent, the importance of scientific and social value in research, and the need for rigorous ethical review processes. This document serves as a crucial guideline for researchers, ethics committees, and institutional review boards to uphold the dignity and rights of individuals participating in medical research. Other options such as regulation of medical device trials, funding requirements for clinical research, and guidelines for animal testing are important aspects of research and clinical practice but do not fall under the primary concerns addressed by the Declaration of Helsinki. The declaration does not specifically dictate financial aspects or animal research protocols; rather, it centers on human research ethics, making option B the most relevant choice regarding the core focus of the Declaration.

8. What is the purpose of masking in clinical trials?

- A. To improve data collection**
- B. To ensure unbiased assessment of outcomes**
- C. To reduce the sample size**
- D. To determine the study's primary variable**

Masking, commonly referred to as blinding, plays a crucial role in clinical trials by ensuring unbiased assessment of outcomes. The process involves keeping certain information hidden from participants and, in some cases, from the researchers themselves. By doing so, it minimizes the risk of bias that can arise from participants' expectations or researchers' influences on the study results. When participants are unaware of which treatment they are receiving, their behavior and reporting of outcomes can be more objective, as they are less likely to be swayed by their knowledge of the treatment. Similarly, when researchers who assess outcomes do not know which participants are in which group, they are less likely to inadvertently influence the results or their interpretation. This precise control helps uphold the integrity of the data collected and enhances the reliability of the conclusions drawn from the study. The other choices, while important in the context of clinical trials, do not specifically capture the primary role of masking. Improving data collection relates more to methodologies and tools rather than the concept of masking. Reducing sample size and determining a study's primary variable do not directly involve masking practices. Therefore, the focus on unbiased outcome assessment distinctly highlights the purpose of masking in clinical trials.

9. What type of trial gathers data without a pre-stated hypothesis?

- A. Exploratory Trial**
- B. Confirmatory Trial**
- C. Therapeutic Trial**
- D. Pharmacokinetic Trial**

The type of trial that gathers data without a pre-stated hypothesis is an exploratory trial. These trials are primarily designed to generate new hypotheses and are often used in the early phases of research to explore potential relationships or outcomes that have not been previously defined. The goal is to investigate and understand phenomena more broadly, rather than to confirm specific effects or relationships as is typical in confirmatory trials. In exploratory trials, researchers may collect a wide range of data to identify which aspects could be relevant for future, more focused studies. This approach allows for a flexible methodology, fostering innovation and the discovery of unexpected results, which can later be tested in more structured trials. In contrast, confirmatory trials are specifically designed to test a pre-defined hypothesis. Therapeutic trials focus on the effectiveness of treatments, and pharmacokinetic trials examine how a drug is absorbed, distributed, metabolized, and excreted in the body. Each of these other types of trials is characterized by having specific aims or hypotheses to test, making exploratory trials unique in their approach.

10. Can CRAs (monitors) review source documents of subjects who have withdrawn consent?

- A. Yes, they can review past documents**
- B. No, they cannot review any documents**
- C. Only if authorized by the investigator**
- D. Only if the documents are de-identified**

CRAs (Clinical Research Associates or monitors) are responsible for overseeing the conduct of clinical trials and ensuring that data collected is accurate and consistent with the regulatory requirements and study protocol. When a subject withdraws consent, it is important to respect their autonomy and confidentiality. However, the review of past documents can be justified in certain contexts. Reviewing past documents after a subject has withdrawn consent can be permissible because this action typically pertains to ensuring that the data already collected up until the point of withdrawal is accurate and has been properly handled. The purpose of this review is to ascertain compliance with the trial protocols and to assess the integrity of the data that has already been gathered prior to the withdrawal of consent. As regulations often allow for the review of data collected before a participant's withdrawal, this supports the rationale behind the correctness of this answer. This practice aligns with regulatory guidelines that prioritize both the ethics of patient consent and the necessity for data integrity in clinical research. Data that has already been obtained typically remains subject to oversight, because it is crucial for ensuring the final analysis and overall validity of the trial's conclusions. Therefore, CRAs are permitted to review source documents of subjects who have previously participated in the study, even after they have opted out.

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!