

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

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1. What is the main purpose of registering a clinical study in a publicly accessible database?
 - A. To ensure all documents are available
 - B. To promote transparency and accountability
 - C. To summarize the findings publicly
 - D. To facilitate recruitment

2. What authority does the Data and Safety Monitoring Board (DSMB) have regarding clinical trials?
 - A. Authorize informed consent
 - B. Recommend protocol changes
 - C. Endorse financial sponsors
 - D. Control participant recruitment

3. When a non-English speaking subject joins a trial and the consent forms are in English, what must be done?
 - A. Translate the forms in-house
 - B. Request the sponsor for a translated version of the consent
 - C. Ask the daughter to translate the documents
 - D. Proceed without signed consent

4. Which group is NOT classified as "vulnerable subjects" in clinical trials?
 - A. Members of the armed forces
 - B. Junior members of the medical profession
 - C. Senior citizens in nursing homes
 - D. Employees of the pharmaceutical industry

5. Which phase of clinical trials emphasizes safety, tolerability, pharmacokinetics, and early measurement of drug activity?
 - A. Phase 1
 - B. Phase 2
 - C. Phase 3
 - D. Phase 4

6. When should a sponsor report serious adverse events (SAEs) to regulatory authorities?
- A. Within 10 calendar days
 - B. Within 15 calendar days
 - C. Within 30 calendar days
 - D. Immediately upon occurrence
7. Prior to archiving a study, where should the documentation of investigational product (IP) destruction at the site be filed?
- A. Institutional Review Board records
 - B. Study files of the Principal Investigator and Sponsor
 - C. Clinical research assistant files
 - D. Government regulatory authority
8. Where should a research subject's responsibilities for study participation be outlined?
- A. Investigator's manual
 - B. Informed Consent Form (ICF)
 - C. Eligibility screening checklist
 - D. Clinical trial agreement
9. Phase IV trials typically require which of the following?
- A. Fewer subjects than Phase III
 - B. More subjects and data collection requirements
 - C. Only one comparator
 - D. No additional data collection
10. According to ICH E8, what type of study is characterized by being randomized, controlled, and aimed at establishing efficacy?
- A. Phase 1 studies
 - B. Therapeutic confirmatory studies
 - C. Exploratory studies
 - D. Bioequivalence studies

Answers

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

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Explanations

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1. What is the main purpose of registering a clinical study in a publicly accessible database?

- A. To ensure all documents are available
- B. To promote transparency and accountability
- C. To summarize the findings publicly
- D. To facilitate recruitment

The main purpose of registering a clinical study in a publicly accessible database is to promote transparency and accountability. This practice allows researchers to disclose their study protocols, objectives, and methodologies before any results are obtained. By doing so, it helps to prevent selective reporting, where only favorable results may be shared with the public or scientific community. A registered study promotes the integrity of the research by ensuring that followers of the field can verify the initial intentions and methods, fostering trust in the research process. While ensuring that all documents are available, summarizing findings publicly, and facilitating recruitment have their own importance in the overall framework of clinical research, they do not capture the overarching need for transparency and accountability that registration fulfills. The act of making study details available creates a comprehensive and open environment regarding clinical trials, ultimately benefiting the scientific community and participants.

2. What authority does the Data and Safety Monitoring Board (DSMB) have regarding clinical trials?

- A. Authorize informed consent
- B. Recommend protocol changes
- C. Endorse financial sponsors
- D. Control participant recruitment

The Data and Safety Monitoring Board (DSMB) plays a critical role in overseeing the safety and efficacy of clinical trials. One of its key authorities is to recommend protocol changes. This authority is essential because the DSMB is responsible for monitoring the data collected during the trial and ensuring that participant safety is prioritized. If the DSMB finds that certain aspects of the trial protocol are not safeguarding participants or if the evolving data suggest that modifications are necessary to improve the trial's design or its potential outcomes, they have the authority to suggest changes. In contrast, while informed consent is an essential part of conducting clinical trials, the DSMB does not have the authority to authorize it; this responsibility typically falls on the investigators and institutional review boards (IRBs). Endorsing financial sponsors is also outside the purview of the DSMB, which is focused on the scientific and ethical conduct of the trial. Similarly, controlling participant recruitment is typically managed by the trial investigators and their study teams rather than the DSMB, although the DSMB may evaluate recruitment strategies as part of their oversight duties.

3. When a non-English speaking subject joins a trial and the consent forms are in English, what must be done?

A. Translate the forms in-house

B. Request the sponsor for a translated version of the consent

C. Ask the daughter to translate the documents

D. Proceed without signed consent

The selected answer highlights the importance of ensuring proper communication and informed consent in clinical trials, particularly when non-English speaking subjects are involved. When the consent forms are only available in English, it is crucial to obtain a translated version to facilitate understanding. This is not just about providing information; it's a regulatory and ethical requirement to ensure that participants can fully comprehend the study details, including risks, benefits, and their rights. Requesting the sponsor for a translated version ensures that the translation is done by professionals who understand the context of the trial and can accurately convey the information in the participant's language. This minimizes the risk of misinterpretation and upholds the integrity of the consent process. In contrast, translations done in-house may not always adhere to official standards, and relying on a relative, like a daughter, to translate could introduce biases and inaccuracies. Proceeding without signed consent is a violation of ethical standards and regulations, undermining the entire framework of conducting clinical research responsibly. Thus, obtaining the translated consent form from the sponsor is the most appropriate and compliant action.

4. Which group is NOT classified as "vulnerable subjects" in clinical trials?

A. Members of the armed forces

B. Junior members of the medical profession

C. Senior citizens in nursing homes

D. Employees of the pharmaceutical industry

In the context of clinical trials, "vulnerable subjects" refer to individuals who may have limited ability to provide informed consent or who may be at a higher risk of coercion or undue influence. These groups often include those who are unable to fully understand the implications of participation or who may be overly reliant on authority figures. Senior citizens in nursing homes may indeed be considered vulnerable due to potential cognitive impairments or dependence on caregivers; however, they are not automatically classified as a vulnerable population in all scenarios. Vulnerability largely depends on the specific circumstances and individual capabilities, not merely on age or living situation. In contrast, members of the armed forces are often considered vulnerable because they may feel compelled to participate in research due to a sense of duty or fear of repercussions. Junior members of the medical profession may face pressure to participate in studies due to hierarchical relationships in hospitals or training programs, making them vulnerable as well. Employees of the pharmaceutical industry are also at risk of coercion due to their professional ties to the study, which can impact their ability to freely consent. Understanding the nuances of who constitutes a vulnerable subject is essential to ensuring the ethical conduct of clinical trials. The classifications are typically context-dependent and should reflect the specific circumstances surrounding the individuals involved.

5. Which phase of clinical trials emphasizes safety, tolerability, pharmacokinetics, and early measurement of drug activity?

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

The emphasis on safety, tolerability, pharmacokinetics, and the initial measurement of drug activity is a hallmark of Phase 1 clinical trials. During this phase, the primary goal is to assess how a new drug affects human subjects. It typically involves a small number of healthy volunteers and focuses on determining whether the drug is safe to use, how it is processed in the body, and what effects it may produce at various dosages. Phase 1 trials are crucial for establishing a baseline understanding of the drug's profile before advancing to larger populations in subsequent trial phases. It lays the groundwork for later studies that will further evaluate the drug's efficacy (typically in Phase 2 and Phase 3 trials) and its long-term safety (in Phase 4 trials). In contrast, later phases prioritize different objectives; for instance, Phase 2 pivots toward assessing efficacy while continuing to monitor safety, Phase 3 expands on this by comparing the new treatment to standard therapies, and Phase 4 occurs after the drug has been approved and focuses on long-term effects and broader population impacts.

6. When should a sponsor report serious adverse events (SAEs) to regulatory authorities?

- A. Within 10 calendar days
- B. Within 15 calendar days
- C. Within 30 calendar days
- D. Immediately upon occurrence

The appropriate timeline for a sponsor to report serious adverse events (SAEs) to regulatory authorities is within 15 calendar days. This timeframe is mandated to ensure that regulatory bodies are promptly informed about events that could have significant implications for participant safety or the integrity of the clinical trial. Submitting SAEs in a timely manner allows for necessary evaluations and potential responses that can mitigate risks to other participants and inform future study conduct. Consistent adherence to the 15-day reporting requirement helps maintain regulatory oversight and facilitates appropriate risk management actions. This period balances the need for timely reporting with the practicalities of gathering complete and accurate information about the event. While other timelines, such as 10 or 30 days, may apply to different contexts or specific conditions, the 15-day window represents the standard expectation in clinical trial regulations for serious adverse events. Immediate reporting may be necessary in exceptionally critical situations, but generally, 15 days is the requisite period for most situations involving SAEs.

7. Prior to archiving a study, where should the documentation of investigational product (IP) destruction at the site be filed?

- A. Institutional Review Board records
- B. Study files of the Principal Investigator and Sponsor
- C. Clinical research assistant files
- D. Government regulatory authority

Filing the documentation of investigational product (IP) destruction in the study files of the Principal Investigator and Sponsor is the most appropriate option because it ensures that both key parties involved in the research maintain a comprehensive and accessible record of all study-related activities and compliance with regulatory requirements. The Principal Investigator is responsible for the conduct of the study and the oversight of all aspects of investigational product management, including its destruction. The Sponsor, who typically funds and oversees the study, also needs an accurate record of IP handling to ensure accountability and transparency. Keeping this documentation together helps maintain an organized archive and allows for easy retrieval should the need arise for audits, inspections, or future reference during the life cycle of the study. The other options are less suitable as they do not centralize the pertinent information for those directly responsible for the study. Institutional Review Board (IRB) records focus more on ethical considerations and approvals rather than operational aspects like product destruction. Filing in clinical research assistant files may not provide a structured environment for retaining essential study documentation, and submitting this information to a government regulatory authority is more appropriate for initial submissions rather than for internal documentation management. Proper filing in the study files ensures that a complete and accurate record is maintained, as mandated by regulatory guidance.

8. Where should a research subject's responsibilities for study participation be outlined?

- A. Investigator's manual
- B. Informed Consent Form (ICF)
- C. Eligibility screening checklist
- D. Clinical trial agreement

The responsibilities of a research subject for study participation should be clearly outlined in the Informed Consent Form (ICF). The ICF is a critical document that ensures potential participants are fully informed about the study, including what is expected of them, the procedures involved, and any risks associated with participation. It serves not only to inform participants but also to protect their rights by ensuring they understand their role in the research. By detailing the subject's responsibilities, the ICF helps ensure that participants know what they need to do to contribute effectively to the research, such as attending visits, following protocols, and reporting any side effects. This clarity is essential for ethical research and compliance with regulatory standards. The ICF is signed by the participant, indicating their understanding and agreement to these outlined responsibilities. While the investigator's manual may contain relevant information for researchers about the study design and protocols, it is not meant for subjects. The eligibility screening checklist is focused on determining if individuals qualify to participate in the research, and the clinical trial agreement is a legal document governing the relationship between sponsors and researchers, without detailing participant responsibilities. Therefore, the ICF is the appropriate document for outlining the responsibilities of research subjects.

9. Phase IV trials typically require which of the following?

- A. Fewer subjects than Phase III
- B. More subjects and data collection requirements**
- C. Only one comparator
- D. No additional data collection

Phase IV trials, also known as post-marketing studies, are critical for monitoring the long-term effects and efficacy of a drug or therapy after it has received regulatory approval. These trials often involve a larger population than Phase III trials to gather extensive safety data and assess how the treatment performs in diverse, real-world scenarios. The greater number of subjects allows researchers to identify rare side effects and evaluate the drug's effectiveness across various demographics and varying health conditions. In addition, the data collection requirements in Phase IV trials are generally more comprehensive, including information on adverse events, patient-reported outcomes, and comparative effectiveness, as they seek to gather data that can inform ongoing clinical use and guide future prescribing practices. This robust design contrasts with some of the other phases, where the primary goal is typically to establish safety and efficacy under controlled conditions. Hence, the need for more subjects and rigorous data collection requirements in Phase IV trials is aligned with their objective of ensuring the ongoing safety and efficacy of the drug in the broader population after its approval.

10. According to ICH E8, what type of study is characterized by being randomized, controlled, and aimed at establishing efficacy?

- A. Phase 1 studies
- B. Therapeutic confirmatory studies**
- C. Exploratory studies
- D. Bioequivalence studies

The type of study characterized by being randomized, controlled, and aimed at establishing efficacy is therapeutic confirmatory studies. These studies are specifically designed to provide evidence for the effectiveness of a treatment by comparing it to a control under carefully controlled conditions. The randomization helps to eliminate bias in treatment assignment, ensuring that the results are reliable and applicable to the broader population. Therapeutic confirmatory studies are typically conducted after exploratory studies have suggested a potential benefit, and they are critical in the drug development process for regulatory approval. They focus on confirming the efficacy of the intervention, which is essential for establishing the therapeutic benefits and justifying the treatment's risk-benefit profile. In contrast, phase 1 studies primarily focus on safety and pharmacokinetics rather than efficacy, exploratory studies are designed to generate hypotheses rather than definitively test treatment effectiveness, and bioequivalence studies are aimed at comparing the bioavailability of two formulations of a drug rather than establishing efficacy.

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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