ACRP GCP and Clinical Trial Principles Practice Test (Sample)

Study Guide

Everything you need from our exam experts!

Table of Contents

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. Why are regulatory submissions necessary for a trial?

A. To obtain and maintain authorization to conduct the trial and ensure ongoing oversight.

B. To recruit participants more quickly.

C. To publish results in journals.

D. To manage the trial budget.

2. Must an AE be related to study drug?

A. Yes.

B. No.

C. Only if SAE.

D. Only if it is expected.

3. What consent form must be used?

A. The version agreed upon by the sponsor

B. The earliest version used in the study

C. A copy of the signed assent form

D. Current IRB-approved version

4. Which documents are considered essential to initiation of a trial?

A. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

B. Investigator CVs; SOPs.

C. Budget and insurance.

D. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

5. Who bears the ultimate responsibility for the conduct of a clinical trial at a site?

A. The Sponsor

B. The Investigator

C. The Regulatory Authority

D. The Monitor

6. Who supervises the research team?

- **A. Principal Investigator (PI)**
- **B. Clinical Research Coordinator (CRC)**
- **C. Sponsor's monitor**
- **D. IRB member**

7. Which documents are typically part of essential documents for initiation?

- **A. Informed consent forms only.**
- **B. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.**
- **C. Study budget and insurance.**
- **D. IP licenses and vendor contracts.**

8. Who designs the protocol?

- **A. CRO.**
- **B. Sponsor.**
- **C. Ethics Committee.**
- **D. Principal Investigator.**

9. Is memorization alone sufficient for the ACRP exam?

- **A. Yes, memorize everything**
- **B. Only memorize GCP**
- **C. Memorization plus practice questions**
- **D. No, application of principles is required**

10. What is a primary endpoint?

- **A. Time to trial completion.**
- **B. Main outcome used to evaluate treatment effect.**
- **C. Total sample size.**
- **D. Any observed adverse event.**

Answers

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

Explanations

1. Why are regulatory submissions necessary for a trial?

A. To obtain and maintain authorization to conduct the trial and ensure ongoing oversight.

B. To recruit participants more quickly.

C. To publish results in journals.

D. To manage the trial budget.

Regulatory submissions establish the legal permission to run a trial and ensure ongoing oversight by authorities and ethics bodies. They document the trial plan, participant protections, site qualifications, and investigator credentials, and they trigger safety and ethical review throughout the study. Through initial approvals, protocol amendments, adverse event reporting, and annual safety or progress updates, regulators verify that the study remains scientifically sound, respects participant rights, and complies with applicable laws and good clinical practice. Without these submissions and the resulting oversight, a trial cannot start or continue legally. Recruiting participants quickly, publishing results, or managing the budget are important but do not provide the required regulatory authorization or ongoing oversight.

2. Must an AE be related to study drug?

A. Yes.

B. No.

C. Only if SAE.

D. Only if it is expected.

An adverse event does not have to be related to the study drug. In clinical trials, investigators collect all untoward medical occurrences that happen to participants and then assess causality to decide if the event is likely related to the drug. Many AEs occur coincidentally or due to other factors such as underlying conditions, other medications, or lifestyle, so they are not considered drug-related. Therefore, the correct answer is that an AE need not be related to the study drug. Notes: seriousness (SAE) and whether an event is expected influence reporting and evaluation, but they do not by themselves determine relatedness.

3. What consent form must be used?

A. The version agreed upon by the sponsor

B. The earliest version used in the study

C. A copy of the signed assent form

D. Current IRB-approved version

Informed consent must use the version of the consent form that has current IRB approval at the time participants are enrolled. The IRB approves the form after reviewing its content, including all required disclosures and protections for participants. If the study makes changes to risks, procedures, or other information, a new IRB-approved version must be used, and participants may need to be re-consented. Using a sponsor's version or an earliest version risks providing outdated or incomplete information and can violate regulatory requirements. A signed assent form is related to minors and, while important, does not replace the standard consent form that the IRB must approve and that governs adult participation. Therefore, the current IRB-approved version is the one that must be used.

4. Which documents are considered essential to initiation of a trial?

A. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

B. Investigator CVs; SOPs.

C. Budget and insurance.

D. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

The essential documents to initiate a trial are those that establish ethical approval, qualified personnel, approved procedures, and a complete record of study documents. Specifically, you need the protocol, informed consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the Trial Master File (TMF) containing the essential documents. Budget and insurance are important for conduct and risk planning, but by themselves they do not establish readiness to start participant enrollment or provide the necessary documentation checklist for initiation. So the best choice is the option that lists protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

5. Who bears the ultimate responsibility for the conduct of a clinical trial at a site?

A. The Sponsor

B. The Investigator

C. The Regulatory Authority

D. The Monitor

Ultimate responsibility for the conduct of a clinical trial at a site rests with the investigator. The investigator is accountable for protecting the rights, safety, and welfare of participants and for carrying out the study in accordance with the protocol, Good Clinical Practice, and applicable laws at that site. This includes obtaining proper informed consent, following procedures as written, managing protocol deviations, and maintaining accurate and complete study documentation. Even when tasks are delegated to sub-investigators or study staff, the investigator remains answerable to the sponsor and to regulatory authorities for how those duties are performed. The sponsor oversees the overall trial design, ethics approvals, and resources, but the day-to-day conduct at the site is the investigator's responsibility. Regulatory authorities provide oversight and inspections, but they do not conduct the study at the site. Monitors support adherence and quality, but ultimate accountability for site conduct lies with the investigator.

6. Who supervises the research team?

A. Principal Investigator (PI)

B. Clinical Research Coordinator (CRC)

C. Sponsor's monitor

D. IRB member

The principal investigator is the person responsible for the overall conduct of the study at the site and for the safety and rights of participants. They ensure protocol adherence, regulatory compliance, informed consent, adverse event reporting, and data integrity, and they supervise the research team to ensure those standards are met. The clinical research coordinator assists with day-to-day tasks under the PI's direction but does not supervise the entire team. The sponsor's monitor provides independent oversight and checks on compliance and data quality during visits, not ongoing supervision of site staff. An IRB member reviews and approves the protocol from an ethics standpoint, but they do not manage trial operations.

7. Which documents are typically part of essential documents for initiation?

A. Informed consent forms only.

B. Protocol, consent forms, IRB/IEC approvals, investigator CVs, SOPs, and the TMF.

C. Study budget and insurance.

D. IP licenses and vendor contracts.

Essential documents for initiation form the complete package that proves regulatory compliance and readiness to start a trial. The full set includes the protocol, informed consent forms, IRB/IEC approvals, investigator qualifications (CVs), standard operating procedures, and the Trial Master File. The protocol outlines the study design and procedures; informed consent forms ensure participants understand the risks and rights; IRB/IEC approvals show ethics review has occurred; investigator CVs verify that the lead investigators are qualified; SOPs ensure consistent processes across sites; and the TMF is the organized collection of all these critical documents used to demonstrate that everything is in place and up to date for initiation. Other items like the study budget and insurance are important for operation and risk management but are not core initiation essential documents; IP licenses and vendor contracts may be needed for conduct but do not comprise the standard initiation document package.

8. Who designs the protocol?

A. CRO.

B. Sponsor.

C. Ethics Committee.

D. Principal Investigator.

The protocol is designed by the sponsor. The sponsor initiates and funds the trial and owns the protocol, which lays out the study's objectives, design (including population, interventions, and endpoints), statistical plan, and safety monitoring. The Principal Investigator at a site carries out the study and can offer practical input, but does not create the governing protocol. The Ethics Committee reviews the protocol for ethical safeguards and participant protection, not its design. A CRO may help run the trial and even contribute to drafting, but ultimate responsibility and ownership of the protocol lie with the sponsor.

9. Is memorization alone sufficient for the ACRP exam?

A. Yes, memorize everything

B. Only memorize GCP

C. Memorization plus practice questions

D. No, application of principles is required

Memorization alone is not enough because the exam measures your ability to apply regulatory principles to real-world trial scenarios. You must translate GCP rules, regulatory timelines, and roles into decisions that protect participants and maintain data integrity. For example, when faced with an SAE, a protocol deviation, or informed consent concerns, you need to determine the correct course of action by applying the principles, not just recalling the rule. Building familiarity with the guidelines is essential, but success comes from applying them to analyze situations, make compliant choices, and justify those decisions. Practice questions help you get used to applying knowledge, but the key is using principles in context.

10. What is a primary endpoint?

A. Time to trial completion.

B. Main outcome used to evaluate treatment effect.

C. Total sample size.

D. Any observed adverse event.

The primary endpoint is the main outcome the study is designed to assess to determine whether the treatment has a meaningful effect. It is the central result used to judge efficacy and is specified before data collection so the study can be properly powered to detect a difference. This outcome drives the statistical analysis and is the primary basis for concluding whether the treatment works. Time to trial completion is about logistics and duration, not the treatment's effect. Total sample size is a planning/design parameter, not an outcome measured to judge efficacy. An observed adverse event is a safety observation and, while important, is typically considered a secondary endpoint or part of safety analyses rather than the primary measure of treatment effect. For example, in a cancer trial the primary endpoint might be progression-free survival, while adverse events would be analyzed separately for safety.

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://acrpgcpclinicaltrialprinciples.examzify.com

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