

ACRP GCP and Clinical Trial Principles Practice Test (Sample)

Study Guide



Everything you need from our exam experts!

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Table of Contents

Copyright	1
Table of Contents	2
Introduction	3
How to Use This Guide	4
Questions	5
Answers	8
Explanations	10
Next Steps	15

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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. Who supervises the research team?**
 - A. Principal Investigator (PI)**
 - B. Clinical Research Coordinator (CRC)**
 - C. Sponsor's monitor**
 - D. IRB member**

- 2. In relation to data integrity, what does the CRC ensure?**
 - A. Real-time data publication.**
 - B. Financial reporting accuracy.**
 - C. Legal compliance of contracts.**
 - D. Accurate, complete, timely documentation.**

- 3. Who manages day-to-day trial operations?**
 - A. CRC**
 - B. PI**
 - C. Sponsor**
 - D. IRB**

- 4. What is randomization?**
 - A. Assignment by chance to reduce bias.**
 - B. Assignment by physician preference.**
 - C. Assignment by patient choice.**
 - D. Assignment by sponsor.**

- 5. What should be done with data queries?**
 - A. Archive promptly and accurately**
 - B. Ignore them**
 - C. Delete data**
 - D. Resolve promptly and accurately**

- 6. Is data fabrication ever allowed?**
 - A. Never**
 - B. Sometimes with approval**
 - C. Only in simulated data**
 - D. Only in blinded studies**

- 7. CBC measures which components of blood?**
- A. Blood glucose and lipids**
 - B. Electrolyte balance**
 - C. Red cells, white cells, hemoglobin, platelets**
 - D. Coagulation factors**
- 8. 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.**
- 9. Which version of ICH E6 is referenced for 2025 exams?**
- A. E6 (R2) with principles aligned to E6 (R3).**
 - B. E6 (R1).**
 - C. E6 (R3).**
 - D. E6 (R2) and E6 (R3) combined.**
- 10. What is the primary responsibility of a monitor?**
- A. Draft the protocol.**
 - B. Verify subject safety and data accuracy.**
 - C. Recruit participants.**
 - D. Manage site budgets.**

Answers

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

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Explanations

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1. 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.

2. In relation to data integrity, what does the CRC ensure?

- A. Real-time data publication.**
- B. Financial reporting accuracy.**
- C. Legal compliance of contracts.**
- D. Accurate, complete, timely documentation.**

The main idea is that a CRC (Cyclic Redundancy Check) detects data errors to protect data integrity. By adding a checksum derived from the data, any corruption that occurs during storage or transmission can be detected when the data is read again and the checksum recalculated. This capability helps ensure that the information recorded in trial documentation stays accurate, complete, and available in a timely manner, because corrupted entries can be identified and corrected before they are used or published. Real-time publication, financial reporting accuracy, and legal compliance are important on their own, but CRCs specifically address detecting unintended data changes, not guaranteeing publication speed or domain-specific compliance.

3. Who manages day-to-day trial operations?

- A. CRC**
- B. PI**
- C. Sponsor**
- D. IRB**

Managing day-to-day trial operations means handling the ongoing, on-site tasks required to run the study—like coordinating visits, obtaining informed consent, collecting data, keeping regulatory documents up to date, and ensuring procedures follow the protocol. This responsibility falls to the Clinical Research Coordinator, who handles these operational details under the supervision of the Principal Investigator. The PI is ultimately accountable for the study's safety and scientific integrity but delegates routine management, the sponsor provides the protocol and oversight, and the IRB focuses on ethics and participant protections rather than daily site activities.

4. What is randomization?

- A. Assignment by chance to reduce bias.**
- B. Assignment by physician preference.**
- C. Assignment by patient choice.**
- D. Assignment by sponsor.**

Randomization is the process of assigning participants to treatment groups by chance, giving each person an equal chance of ending up in any group. This approach helps ensure that the groups are comparable at the start of the study, so differences in outcomes are more likely due to the treatment itself rather than preexisting differences between participants. By balancing both known factors (like age or disease severity) and unknown factors across groups, randomization reduces selection bias and confounding, which underpins the validity of statistical comparisons and supports conclusions from intention-to-treat analyses. Methods can include computer-generated random numbers or randomization schemes like blocks or stratification to maintain balance over time or on key characteristics. In contrast, assigning by physician preference, patient choice, or sponsor decisions can introduce bias by allowing systematic differences between groups, which undermines the trial's ability to attribute outcomes to the treatment.

5. What should be done with data queries?

- A. Archive promptly and accurately**
- B. Ignore them**
- C. Delete data**
- D. Resolve promptly and accurately**

Data queries are raised when data values don't align with the source documents or show inconsistencies, and the aim is to fix those issues so the dataset remains accurate and auditable. Resolving them promptly and accurately ensures the data reflect the true study results and keeps the analysis plan on track. The process involves checking the source data or system logs, applying any approved corrections, and documenting exactly what was changed, who approved it, and when. Doing this quickly minimizes delays in database lock and maintains data quality throughout the trial, which is essential for regulatory compliance and reliable conclusions. Archiving is part of the data lifecycle, but it should come after queries are resolved; archiving an open issue would hide the problem. Ignoring queries or deleting data would leave inaccuracies in the record and break integrity and traceability.

6. Is data fabrication ever allowed?

- A. Never**
- B. Sometimes with approval**
- C. Only in simulated data**
- D. Only in blinded studies**

Maintaining data integrity means every data point in a trial truly reflects what was observed and is recorded accurately, verifiably, and traceably. Fabricating data—making up results or altering data to fit a desired outcome—violates ethical standards, GCP requirements, and participant safety. It undermines the scientific validity of the study, misleads investigators, sponsors, and regulators, and can lead to incorrect risk assessments or inappropriate approvals. Because there is no legitimate scenario where false data are acceptable in a clinical trial, data fabrication is never allowed. Simulated data can be used for training or methodological development, but it must be clearly labeled as simulated and kept separate from real trial data; it does not replace actual observations in a study.

7. CBC measures which components of blood?

- A. Blood glucose and lipids**
- B. Electrolyte balance**
- C. Red cells, white cells, hemoglobin, platelets**
- D. Coagulation factors**

A complete blood count focuses on the cellular components of blood: red blood cells, white blood cells, and platelets, with hemoglobin concentration reported as part of the panel. These elements are quantified to assess oxygen-carrying capacity (via red cells and hemoglobin), immune status (white cells), and clotting potential (platelets). It does not measure metabolic substances like glucose or lipids, electrolytes, or coagulation factors. Glucose and lipids come from metabolic panels, electrolytes from a chemistry panel, and coagulation factors from specialized clotting studies (PT/INR, aPTT).

8. 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.

9. Which version of ICH E6 is referenced for 2025 exams?

- A. E6 (R2) with principles aligned to E6 (R3).**
- B. E6 (R1).**
- C. E6 (R3).**
- D. E6 (R2) and E6 (R3) combined.**

The question tests your understanding of how the ICH E6 guidelines are used for exams during a transition period. For 2025 exams, the referenced standard is E6 in its R2 revision, but the exam content is aligned to the principles of E6(R3). This means you're measured against the established requirements of R2 while also incorporating the newer ideas and expectations from R3—such as stronger emphasis on risk-based quality management and data integrity—without fully switching to R3 as the sole baseline. E6(R1) is outdated and not the reference used, and treating both R2 and R3 as completely separate standards isn't how the exam is structured; it uses R2 as the base with alignment to R3.

10. What is the primary responsibility of a monitor?

- A. Draft the protocol.**
- B. Verify subject safety and data accuracy.**
- C. Recruit participants.**
- D. Manage site budgets.**

The monitor's main job is to ensure subject safety and data accuracy. At trial sites, monitors verify that participants are protected—consent is properly obtained, eligibility is correct, and adverse events are reported promptly and handled according to the protocol. They also perform source data verification and cross-check study data against source documents to confirm accuracy and completeness, ensuring the trial data reliably reflect what actually happened. This combination protects participants while safeguarding the integrity and reliability of the trial results, which is the central purpose of monitoring. Drafting the protocol is typically done by the sponsor or study designers, not the monitor. Recruiting participants is the responsibility of site staff or investigators, not the monitor. Managing site budgets falls under site management or finance, not monitoring.

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://acrpgcpcclinicaltrialprinciples.examzify.com>

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

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