# Good Clinical Practice E6 (R3) Practice Test (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. Which procedures are necessary for the use of computerized systems in trials?**

**A. Expediting data processing.**

**B. Establishing guidelines for operation, security, and data management.**

**C. Only ensuring accessibility.**

**D. Only training staff.**

**2. What is the purpose of risk communication in clinical trials?**

**A. To document and communicate identified risks and mitigating activities to those involved or affected, facilitating risk review and continual improvement.**

**B. To recruit participants.**

**C. To design the protocol.**

**D. To ensure regulatory submission deadlines.**

**3. Which group is responsible for adopting the guideline under Step 4 in the ICH process?**

**A. ICH Steering Committee**

**B. ICH Expert Working Group**

**C. ICH Assembly of Regulators**

**D. Regulatory Members of the ICH Assembly**

**4. Which statement describes variation in trial scale and cost?**

**A. They vary in scale but not in cost.**

**B. They are always uniform.**

**C. They vary widely in scale, complexity, and cost.**

**D. They are never expensive.**

**5. What should be disclosed about anticipated expenses related to trial participation?**

**A. Any anticipated expenses related to trial participation**

**B. Only travel expenses**

**C. No expenses are disclosed**

**D. Expenses are billed to the participant's insurer**

**6. How are participant identities handled in publications of trial results?**

- **A. Participant identity remains confidential and records are not publicly available.**
- **B. Participant identities are published with the trial results.**
- **C. Records identifying participants are publicly available with consent.**
- **D. Only aggregated data is released without confidentiality safeguards.**

**7. Source records should include which of the following?**

- **A. Pertinent observations on each trial participant**
- **B. The sponsor's budget**
- **C. The site address**
- **D. The regulatory approvals**

**8. Which statement about IRB/IEC membership is accurate?**

- **A. The IRB/IEC should consist of at least five members.**
- **B. The IRB/IEC should include at least one independent member.**
- **C. The IRB/IEC should consist of at least five members, include at least one member whose primary interest is not in medical sciences, and have at least one independent member.**
- **D. The IRB/IEC must be composed of nine members.**

**9. How should trial issues be escalated and followed up by the sponsor?**

- **A. Delay escalation until the end of the trial.**
- **B. The sponsor should ensure appropriate and timely escalation and follow-up of issues to implement necessary actions.**
- **C. Only investigators handle escalation.**
- **D. Escalation should be avoided unless required.**

**10. What are important protocol deviations in clinical trials?**

**A. Deviations are never important.**

**B. Deviations must be ignored.**

**C. Important deviations are those that may significantly impact completeness, accuracy, and reliability of data or affect a participant's rights, safety, or well-being.**

**D. Deviations refer only to scheduling visits.**

# Answers

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

# Explanations

## 1. Which procedures are necessary for the use of computerized systems in trials?

**A. Expediting data processing.**

**B. Establishing guidelines for operation, security, and data management.**

**C. Only ensuring accessibility.**

**D. Only training staff.**

**The key idea is that computerized systems used in trials must have formal procedures that cover how the system is operated, who can access it and under what controls, and how data are managed throughout the study. This combination ensures the system functions reliably and data remain accurate, complete, and attributable. Establishing guidelines for operation, security, and data management is the best choice because it encompasses everything regulators expect: clear instructions for using the system (so everyone uses it consistently and correctly), robust security and access controls (to prevent unauthorized use and to maintain traceability through audit trails), and solid data management practices (covering data collection, validation, entry, storage, backup, and retention). Together, these elements protect data integrity and support compliant, auditable trial conduct. The other options focus on only one aspect or overlook critical safeguards: expediting data processing isn't the regulatory aim, accessibility alone ignores security and integrity, and training alone doesn't address how the system operates, secures data, or manages data over the study lifecycle.**

## 2. What is the purpose of risk communication in clinical trials?

**A. To document and communicate identified risks and mitigating activities to those involved or affected, facilitating risk review and continual improvement.**

**B. To recruit participants.**

**C. To design the protocol.**

**D. To ensure regulatory submission deadlines.**

**Risk communication in clinical trials is about sharing information on identified risks and the actions taken to mitigate them with everyone who needs to know—investigators, trial staff, sponsors, oversight bodies, and, when appropriate, participants. This keeps all stakeholders informed, supports ongoing review of risks, and drives continual improvement of safety measures and trial processes. It's a continuous, lifecycle activity that helps protect participants and preserve trial integrity by enabling timely decisions and coordinated responses to new or changing risks. It's not primarily about recruiting participants, designing the protocol, or meeting submission deadlines. For example, when a safety signal is identified, risk communication involves updating the risk register, informing sites and committees, and adjusting training, SOPs, and consent materials as needed.**

## 3. Which group is responsible for adopting the guideline under Step 4 in the ICH process?

**A. ICH Steering Committee**

**B. ICH Expert Working Group**

**C. ICH Assembly of Regulators**

**D. Regulatory Members of the ICH Assembly**

**Step 4 of the ICH process is the formal adoption of the guideline by the regulatory authorities across the ICH regions. The group responsible for this adoption is the regulatory members of the ICH Assembly. They review the draft, consider public feedback, and then officially adopt the guideline for implementation in their jurisdictions. The drafting work is done by the Expert Working Group, while the Steering Committee guides governance and oversight; neither of these perform the formal adoption.**

## 4. Which statement describes variation in trial scale and cost?

**A. They vary in scale but not in cost.**

**B. They are always uniform.**

**C. They vary widely in scale, complexity, and cost.**

**D. They are never expensive.**

**Trials differ a lot in size, design, and resources required. Depending on the research question, you might have a small, simple, short study at a single site or a large, multicenter, long-term trial with complex endpoints, extensive data collection, and intensive monitoring. Because of these varying factors—number of sites, duration, endpoints, data management needs, and regulatory requirements—the scale, complexity, and cost can span a wide range. So the statement that they vary widely in scale, complexity, and cost most accurately reflects how clinical trials operate. If a statement suggested only the scale varies or that trials are always uniform or never expensive, it would ignore the clear ways trials differ in design and resource needs, which isn't consistent with how trials are planned and conducted.**

## 5. What should be disclosed about anticipated expenses related to trial participation?

**A. Any anticipated expenses related to trial participation**

**B. Only travel expenses**

**C. No expenses are disclosed**

**D. Expenses are billed to the participant's insurer**

**When obtaining consent, you must disclose all reasonably foreseeable costs that could be incurred by participating in the trial. This means providing a clear statement of anticipated expenses, such as travel, accommodations, tests or procedures not covered by the sponsor, and any other out-of-pocket costs, along with information about who will pay or reimburse them (for example, what the insurer might cover and what the sponsor will or will not reimburse). This full disclosure helps the participant make an informed decision without unexpected financial burdens. Limiting disclosure to travel misses other potential costs; saying no expenses will be disclosed would deprive the participant of essential information; and stating that expenses are billed to the insurer alone does not convey the need to inform about all anticipated costs and who bears them.**

## 6. How are participant identities handled in publications of trial results?

**A. Participant identity remains confidential and records are not publicly available.**

**B. Participant identities are published with the trial results.**

**C. Records identifying participants are publicly available with consent.**

**D. Only aggregated data is released without confidentiality safeguards.**

**Participant privacy is upheld by keeping identities confidential in publications; only de-identified or aggregated data are shared, and records with identifying details are not made publicly accessible. This protects participants from being recognized and aligns with ethical and regulatory requirements that emphasize confidentiality in trial reporting. Publishing identifiable information would breach confidentiality and consent norms. Even with consent, standard practice is to minimize identifiability in public reports to prevent potential harm. Releasing records identifying participants publicly would introduce unnecessary risk, and stating that data are released without confidentiality safeguards contradicts the fundamental protections in trial ethics.**

## 7. Source records should include which of the following?

**A. Pertinent observations on each trial participant**

**B. The sponsor's budget**

**C. The site address**

**D. The regulatory approvals**

**Source records are the original, verifiable documents that capture the actual observations and data for each trial participant. They provide the evidence that the data entered into case report forms are accurate and complete, by listing pertinent observations such as vital signs, physical findings, lab results, and other measurements or notes made during the participant's participation. Because these records document what was observed about every participant, they must contain the relevant observations for each person. Items like the sponsor's budget, the site address, or regulatory approvals belong in administrative or regulatory files, not in source records. Keeping the pertinent observations in source records ensures traceability and data integrity across the study.**

**8. Which statement about IRB/IEC membership is accurate?**

**A. The IRB/IEC should consist of at least five members.**

**B. The IRB/IEC should include at least one independent member.**

**C. The IRB/IEC should consist of at least five members, include at least one member whose primary interest is not in medical sciences, and have at least one independent member.**

**D. The IRB/IEC must be composed of nine members.**

**The essential idea here is that an IRB/IEC must be diverse and independent to review research properly and protect participants. Good practice requires a board of at least five members with backgrounds that cover different perspectives, including both scientific and non-scientific viewpoints, and at least one member who is independent of the institution or sponsor. This option matches that standard by stating the board should have at least five members and also include a member whose primary interest is not in medical sciences (providing a non-scientific or lay perspective) as well as at least one independent member (not affiliated with the institution or sponsor). Together, these requirements help ensure the IRB can assess risks, informed consent, and participant protections without undue influence or blind spots. Why the other statements aren't the best fit: one option mentions the minimum of five but doesn't require an independent or non-scientific member, leaving the board potentially lacking crucial diversity and impartial oversight. Another option requires independence but doesn't specify the minimum size or the non-scientific perspective. The last option fixes a nine-member size, which isn't a mandated number.**

**9. How should trial issues be escalated and followed up by the sponsor?**

**A. Delay escalation until the end of the trial.**

**B. The sponsor should ensure appropriate and timely escalation and follow-up of issues to implement necessary actions.**

**C. Only investigators handle escalation.**

**D. Escalation should be avoided unless required.**

**In Good Clinical Practice, the sponsor has the ongoing duty to oversee the trial and protect participant safety and data integrity. When issues arise—anything that could affect safety, data quality, or compliance—the sponsor must have a clear path to escalate them to the right people at the right time and then actively follow up to ensure actions are taken and effective. This means promptly notifying appropriate stakeholders, assigning owners, initiating corrective and preventive actions, setting timelines, and verifying that those actions actually resolved the issue. A formal escalation and follow-up process helps prevent risks from escalating, ensures regulatory and ethical obligations are met, and provides auditable evidence that problems were addressed. Delaying escalation until the end of the trial would miss opportunities to mitigate risk and could compromise participant safety and data integrity. Escalation is not the sole responsibility of investigators; the sponsor bears the responsibility for oversight and timely intervention. And escalation should not be avoided or postponed unless there's no alternative—proactive, documented action is the aim to effectively manage trial issues.**

## 10. What are important protocol deviations in clinical trials?

**A. Deviations are never important.**

**B. Deviations must be ignored.**

**C. Important deviations are those that may significantly impact completeness, accuracy, and reliability of data or affect a participant's rights, safety, or well-being.**

**D. Deviations refer only to scheduling visits.**

**A key idea in good clinical practice is that not all deviations from the protocol are equal, and only those with potential to affect data quality or participant safety require careful handling. Important protocol deviations are the ones that may significantly impact the completeness, accuracy, and reliability of the trial data or affect a participant's rights, safety, or well-being. Because of this, they should be recognized, documented, risk-assessed, and managed or reported according to the protocol and regulatory requirements, with appropriate corrective actions. This isn't about every tiny misstep. Minor deviations that don't threaten data integrity or safety may be acceptable with proper documentation, but deviations that could alter results or put participants at risk must be addressed. It's also incorrect to think deviations are only about scheduling visits; deviations can involve procedures, timing of assessments, dosing, eligibility criteria, data collection, and more, any of which could impact the trial.**

# 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://goodclinicalpracticee6r3.examzify.com**

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