

# INTERNATIONAL COUNCIL FOR HARMONISATION (ICH) E6 PRACTICE EXAM (SAMPLE) STUDY GUIDE



## SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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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. Which best describes the responsibilities for adverse event reporting?**
  - A. Handled solely by clinical research organizations
  - B. Only required after trial completion
  - C. Primarily the responsibility of the sponsor
  - D. Ignored if no incidents occur
- 2. How long must study-related records be maintained after drug approval in the U.S. according to ICH E6?**
  - A. One year
  - B. Two years
  - C. Five years
  - D. Indefinitely
- 3. What is the required maintenance period for device investigation records according to FDA regulations?**
  - A. One year
  - B. Two years
  - C. Three years
  - D. Five years
- 4. Which of the following roles has direct access to subject medical records under ICH E6 requirements?**
  - A. Insurance representatives
  - B. Regulatory authority representatives
  - C. Trial monitors only
  - D. Marketing teams
- 5. In emergency situations, if prior consent is not possible, what should happen according to ICH guidelines?**
  - A. Only verbal consent should be necessary.
  - B. Consent from the legally acceptable representative should be sought if available.
  - C. Subjects should not be enrolled without prior consent.
  - D. Subjects must be informed after enrollment only.

- 6. What is the Clinical Study Report (CSR) primarily used for in clinical trials?**
- A. A comprehensive document that summarizes the various trial protocols
  - B. A document that contains the trial budget and funding details
  - C. A comprehensive document that summarizes the conduct and results of a clinical trial
  - D. A report that provides participant demographics only
- 7. According to FDA regulations, what specific document must an IRB keep copies of?**
- A. Trial protocol amendments
  - B. All research proposals reviewed
  - C. Investigator's brochure
  - D. Curriculum vitae of each investigator
- 8. What constitutes a serious adverse event (SAE)?**
- A. Any adverse event resulting in a temporary medical condition
  - B. Any adverse event that results in death, is life-threatening, requires hospitalization, or causes significant disability
  - C. Minor side effects reported by participants
  - D. Events that lead to further research study
- 9. How long must IRB records be retained after the completion of a trial according to ICH and FDA?**
- A. Two years
  - B. Three years
  - C. Five years
  - D. Indefinitely
- 10. Which criteria is essential for selecting a clinical trial site?**
- A. Location solely based on proximity to the investigator
  - B. Popularity of the site among participants
  - C. Suitability for the trial population and resources available
  - D. Size of the site facility

## **Answers**

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

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## **Explanations**

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## 1. Which best describes the responsibilities for adverse event reporting?

- A. Handled solely by clinical research organizations
- B. Only required after trial completion
- C. Primarily the responsibility of the sponsor**
- D. Ignored if no incidents occur

*The responsibilities for adverse event reporting are primarily the responsibility of the sponsor. This is grounded in the principles set forth by regulatory authorities and the ICH E6 guidelines, which outline the obligations of sponsors to ensure the safety and welfare of trial participants. The sponsor is responsible for the overall conduct of the clinical trial, including monitoring and reporting any adverse events that may arise during the study. This includes the need to evaluate and report any adverse events to regulatory bodies as required, ensuring that participant safety is prioritized throughout the trial. In addition, the sponsor is responsible for maintaining oversight of both the clinical trial process and the data collected, which includes adequately training staff to recognize and report adverse events. This responsibility extends beyond just during the active trial phase; they must continuously monitor for adverse events even if no incidents have been reported initially. This diligence helps in identifying any potential risks associated with the investigational product, thus contributing to public safety and informed decision-making. The other options do not accurately reflect the responsibilities outlined in ICH E6. For instance, stating that adverse event reporting is handled solely by clinical research organizations disregards the sponsor's ultimate accountability. Similarly, claiming that reporting is only required after trial completion contradicts the need for ongoing monitoring during the trial. Lastly*

## 2. How long must study-related records be maintained after drug approval in the U.S. according to ICH E6?

- A. One year
- B. Two years**
- C. Five years
- D. Indefinitely

*According to ICH E6 guidelines, study-related records must be maintained for a minimum of two years after the date a marketing application is approved for the drug in the U.S. This requirement is in place to ensure that adequate records are available to support claims made in the marketing application and to allow for post-marketing surveillance and further assessment of the drug's safety and efficacy. The two-year retention period strikes a balance between the need for record accessibility and practical considerations concerning data management and storage. While longer retention periods may be advisable for certain records, particularly in cases of ongoing monitoring or for products that have raised significant safety concerns, the two-year guideline sets a foundational requirement that must be adhered to following drug approval. This timeframe enables regulatory bodies and other stakeholders to follow up and analyze the results related to the drug following its entry into the market.*

**3. What is the required maintenance period for device investigation records according to FDA regulations?**

- A. One year
- B. Two years**
- C. Three years
- D. Five years

*According to FDA regulations, the required maintenance period for device investigation records is two years following the completion of a clinical investigation. This period ensures that all documentation related to the investigation is readily available for review, which is crucial for regulatory compliance and potential audits. The maintenance of records for this duration helps to uphold data integrity and supports the accountability of clinical investigations in the event of inquiries or compliance checks by regulatory authorities. The specified two-year timeframe strikes a balance between ensuring adequate oversight and the practicalities of record-keeping in clinical research. This is aligned with FDA's commitment to patient safety and the integrity of products entering the healthcare market.*

**4. Which of the following roles has direct access to subject medical records under ICH E6 requirements?**

- A. Insurance representatives
- B. Regulatory authority representatives**
- C. Trial monitors only
- D. Marketing teams

*Under ICH E6 requirements, regulatory authority representatives have a critical role in ensuring the safety and efficacy of clinical trials. They possess the authority to access various documents associated with the conduct of the study, which includes reviewing subject medical records when necessary. This access is vital for regulatory oversight, as it allows these representatives to verify that the trial is being conducted in accordance with regulatory standards and that the rights and welfare of the subjects are adequately protected. The role of regulatory authority representatives is specifically supported by the principles outlined in ICH E6, which emphasizes the importance of transparency and oversight in clinical trials. This access is typically governed by strict confidentiality and ethical considerations, ensuring that subjects' privacy is maintained while providing necessary information for regulatory purposes. In contrast, other roles listed, such as insurance representatives, trial monitors, and marketing teams, do not generally have direct access to subject medical records under these guidelines. Insurance representatives primarily focus on assessing claims related to the study, trial monitors oversee the compliance and progress of the study but do not require access to individual medical records, and marketing teams handle promotional activities rather than regulatory oversight, which means they do not need such access.*

**5. In emergency situations, if prior consent is not possible, what should happen according to ICH guidelines?**

- A. Only verbal consent should be necessary.
- B. Consent from the legally acceptable representative should be sought if available.**
- C. Subjects should not be enrolled without prior consent.
- D. Subjects must be informed after enrollment only.

*According to ICH guidelines, in emergency situations where obtaining prior consent is not feasible, it is crucial to seek consent from a legally acceptable representative if one is available. This approach acknowledges the ethical principle of respect for persons and the right to make decisions regarding participation in clinical research. In cases where immediate intervention is necessary to protect the health or life of a potential subject, and obtaining consent from the individual is impractical, relying on a legally acceptable representative ensures that the individual's interests and rights are still protected. This representative can provide the necessary consent on behalf of the participant, maintaining compliance with ethical standards. Furthermore, it's also important to inform the subject, or their representative, of their involvement in the study as soon as possible after the intervention, which underscores the commitment to ethical research conduct.*

**6. What is the Clinical Study Report (CSR) primarily used for in clinical trials?**

- A. A comprehensive document that summarizes the various trial protocols
- B. A document that contains the trial budget and funding details
- C. A comprehensive document that summarizes the conduct and results of a clinical trial**
- D. A report that provides participant demographics only

*The Clinical Study Report (CSR) is primarily utilized to provide a comprehensive document that summarizes the conduct and outcomes of a clinical trial. This report encompasses essential aspects such as the study's objectives, methodology, results, and a detailed analysis of findings, which is crucial for regulatory submissions, peer reviews, and publication in scientific journals. The CSR integrates all significant elements of the study, including the design, recruitment, interventions, statistical methods, and any adverse events observed during the trial, allowing stakeholders, such as regulatory authorities, sponsors, and the scientific community, to assess the robustness and validity of the study. By offering a thorough synopsis, the CSR plays a critical role in the overarching process of drug development, ensuring transparency and accountability, and providing the necessary context for understanding the trial's implications for clinical practice and further research.*

**7. According to FDA regulations, what specific document must an IRB keep copies of?**

- A. Trial protocol amendments
- B. All research proposals reviewed**
- C. Investigator's brochure
- D. Curriculum vitae of each investigator

*The specific document that an Institutional Review Board (IRB) must keep copies of, as per FDA regulations, is all research proposals reviewed. This requirement is in place to ensure that the IRB can effectively monitor and evaluate the ethical considerations associated with the research being conducted. Keeping copies of all reviewed research proposals allows the IRB to establish a comprehensive record of the studies it has evaluated, enabling them to uphold their oversight responsibilities and ensure compliance with federal regulations. This documentation serves critical purposes, including facilitating future reviews, supporting the institution's adherence to ethical standards, and providing necessary information in the event of audits or investigations. By maintaining comprehensive records of proposals, the IRB can also ensure that informed consent, potential risks, and the scientific validity of the research are consistently addressed across all evaluations.*

**8. What constitutes a serious adverse event (SAE)?**

- A. Any adverse event resulting in a temporary medical condition
- B. Any adverse event that results in death, is life-threatening, requires hospitalization, or causes significant disability**
- C. Minor side effects reported by participants
- D. Events that lead to further research study

*A serious adverse event (SAE) is defined by its potential to significantly impact a person's health scenario. The correct choice highlights the critical conditions that classify an event as serious: it must result in death, be life-threatening, require hospitalization, or lead to significant disability. These criteria are essential in the clinical research field because they help ensure participant safety by requiring immediate reporting and action. Understanding these classifications aids in monitoring and evaluating the safety of investigational products, thus ensuring comprehensive risk management and adherence to regulatory guidelines. The other options do not align with the standard definitions of serious adverse events. For instance, a temporary medical condition may not meet the severity criteria necessary to be classified as an SAE. Similarly, minor side effects experienced by participants are generally not classified as serious events if they do not meet the established criteria. Lastly, while events leading to further research study may indicate ongoing monitoring or investigation, they do not define an SAE by the aforementioned critical parameters.*

**9. How long must IRB records be retained after the completion of a trial according to ICH and FDA?**

- A. Two years
- B. Three years**
- C. Five years
- D. Indefinitely

*The requirement for retaining Institutional Review Board (IRB) records after the completion of a clinical trial is set forth in both ICH guidelines and FDA regulations, which specify a retention period of three years. This timeframe begins from the date the trial is completed, ensuring that all documentation pertinent to the trial's ethical oversight, protocol amendments, and informed consent processes is preserved for review and accountability. Retention of records for three years aligns with the need for maintaining adequate documentation in case of audits, inspections, or inquiries related to the trial. This facilitates transparency and supports the integrity of the research process, allowing for potential future reference in disputes or evaluations of the trial's conduct. In contrast, other retention periods—such as two, five, or indefinite—do not meet the specific regulatory requirements established by the ICH and FDA for clinical trials. A period of two years falls short of the required timeframe, while five years exceeds it unnecessarily for the purpose of IRB documentation. Retaining records indefinitely is also impractical and not mandated. Therefore, the three-year retention period is the standard established for ensuring proper oversight of clinical research activities.*

**10. Which criteria is essential for selecting a clinical trial site?**

- A. Location solely based on proximity to the investigator
- B. Popularity of the site among participants
- C. Suitability for the trial population and resources available**
- D. Size of the site facility

*Selecting a clinical trial site is a critical decision that directly impacts the success of the study. The essential criterion is the suitability for the trial population and the resources available at the site. This includes evaluating whether the site has access to the specific patient demographics required for the trial, the necessary medical facilities, equipment, and personnel that align with the trial's needs. The trial population is particularly important because the effectiveness and validity of the study's outcomes hinge on enrolling participants who meet the study criteria and can adhere to the protocol. Additionally, resources available at the site, such as experienced staff and operational capabilities, ensure that the trial can be conducted efficiently and with high quality. In contrast, factors like proximity to the investigator or the site's popularity among participants may influence site selection but do not address the fundamental needs for the trial's objectives. Similarly, while the size of the facility can play a role in logistics, it is not a primary factor without ensuring that it suits the specific demands of the trial population and has adequate resources to support the study effectively.*

## 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](mailto:hello@examzify.com).

Or visit your dedicated course page for more study tools and resources:

<https://iche6.examzify.com>

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

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