

QUESTIONS

1. Provide a definition of a clinical trial.
2. What are the general goals of phase I, II, and III clinical trials?
3. What is polymorphism?
4. Why is it often necessary to develop new methods of synthesis upon converting a lab scale preparation of a candidate compound to a commercial scale synthesis?
5. What are four types of delivery methods that can be used to administer a candidate compound?
6. What is the purpose of an enteric coating on a tablet?
7. What is an excipient?
8. What is the purpose of the “push chamber” in a two chambered osmotic pump delivery system?
9. What are the three major sections of an investigational new drug (IND) application?
10. What is the purpose of an institutional review board (IRB)?
11. What is allometric scaling?
12. What is a “3 + 3” phase I study?
13. What is the purpose of an interim analysis in a clinical trial?
14. What is the purpose of a stopping rule in a clinical trial?
15. Why would an organization choose to run a phase III clinical trial as an equivalency trial rather than attempt to show superiority over the standard of care?
16. What are the advantages of a cross-over study?
17. How are adaptive clinical trials different from standard clinical trials?

References

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