Assignment 1

The due date for submitting this assignment has passed.

Due on 2020-02-12, 23:59 IST.

Assignment 1 Overview of Indian regulatory system

1. A pharmaceutical company, ABC, which conducts a clinical trial with already approved new drug in the country. The company has applied for an extension to the duration of the trial. How would you classify the type of the regulatory application and what is the process of handling this type of application?

- Approval
- Amendment
- Initial approval
- Application for initial approval

2. The trial involves a total of 450 participants. The results will be published in journals, and the trial will be registered with EMA. What is the expected timeline for this type of trial to be completed?

- 60 days
- 90 days
- 120 days
- 180 days

3. The trial involves a total of 250 participants. The trial will be registered with FDA. The participants will be randomized into two groups. Are the groups equally balanced? Why?

- Yes, 125 participants in each group
- No, the groups are not equally balanced
- Cannot be determined from the information provided

4. What is the role of the IRB in a clinical trial? What are the key responsibilities of the IRB in this context?

- Ensure compliance with ethical standards
- Review and approve the protocol
- Monitor the trial
- Report adverse events

5. The trial involves the use of a new drug. What is the role of the ethics committee in this context?

- Ethical review of the trial
- Approval of the trial protocol
- Monitoring of the trial
- Reporting of adverse events

6. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

7. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

8. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

9. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

10. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

11. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

12. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

13. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

14. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

15. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

16. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

17. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

18. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

19. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

20. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

21. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

22. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

23. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

24. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

25. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

26. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations

27. The trial involves the use of a new drug. What is the role of the patients in this context?

- Consent to participate
- Protection of their rights
- Reporting of adverse events
- Improvement of the treatment

28. The trial involves the use of a new drug. What is the role of the sponsor in this context?

- Financing the trial
- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations

29. The trial involves the use of a new drug. What is the role of the investigators in this context?

- Conducting the trial
- Reporting of adverse events
- Ensuring compliance with regulations
- Protection of the patients' rights

30. The trial involves the use of a new drug. What is the role of the regulatory authorities in this context?

- Approval of the drug
- Monitoring of the trial
- Reporting of adverse events
- Enforcement of compliance with regulations