STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted from the academic year 2019 – 2020 & thereafter)

M. Sc. DEGREE EXAMINATION, APRIL 2024
BIOINFORMATICS
FOURTH SEMESTER

COURSE : ELECTIVE
PAPER : BASICS OF CLINICAL RESEARCH MANAGEMENT
SUBJECT CODE : 19BI/PE/CR15
TIME : 3 HOURS MAX. MARKS: 100

SECTION – A

ANSWER ALL QUESTIONS (20 X 1=20)

1. Define clinical research.
2. What is the Nuremberg Code?
3. Name two major aspects of pharmacodynamics.
4. What is Good Clinical Practice (GCP)?
5. Identify one database used for drug search.
6. What does IND stand for?
7. Explain the term "pharmacokinetics."
8. What is the purpose of FDA audits?
9. Define the role of Ethics Committees in clinical trials.
10. What is a Clinical Trial Protocol?
11. Mention one statistical method used in clinical data analysis.
12. What is Pharmacovigilance?
13. Name an emerging technology in drug discovery.
14. What does ANDA stand for?
15. Describe the purpose of a Data Safety Monitoring Board (DSMB).
16. What is a CRF?
17. Mention one regulation from the Declaration of Helsinki.
18. Explain the concept of "drug discovery."
19. What is the significance of preclinical testing?
20. Name one key function of the European Regulatory Affairs.

SECTION – B

ANSWER ANY FOUR QUESTIONS. EACH ANSWER SHOULD NOT EXCEED 500 WORDS. ALL QUESTIONS CARRY EQUAL MARKS. (4 x 10 = 40)

21. Discuss the historical evolution of clinical trials, highlighting the significance of the Declaration of Helsinki.
22. Explain the process of drug discovery and development, focusing on the importance of pharmacokinetics and pharmacodynamics.
23. Describe the US FDA's role in clinical research regulation, specifically focusing on IND and NDA processes.
24. Detail the design and importance of Clinical Trial Protocols, including SAE reconcilition.
25. Outline the stages and key considerations in clinical data management (CDM), emphasizing on data validation and quality assurance.

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26. Discuss the impact of emerging technologies on drug discovery and development, providing examples.
27. Explain the regulatory landscape in India for clinical research, focusing on Schedule Y and its implications for drug approval.

SECTION – C

ANSWER ANY TWO QUESTIONS. EACH ANSWER SHOULD NOT EXCEED 1200 WORDS. ALL QUESTIONS CARRY EQUAL MARKS. (2 x 20 = 40)

28. Assess key challenges in biopharmaceutical development, focusing on global regulations and clinical research management's response.
29. Explain the role of statistics in clinical trials from design to reporting, and how they ensure research integrity.
30. Address ethical considerations in clinical research, emphasizing Ethics Committees and IRBs, and the treatment of special populations.
31. Evaluate the influence of global regulators and international guidelines on clinical research, especially ICH and GCP, and their role in harmonizing clinical trial practices.

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