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

SUBJECT CODE: 19BI/PE/CR15

M. Sc. DEGREE EXAMINATION, APRIL 2022
BIOINFORMATICS
FOURTH SEMESTER

COURSE : ELECTIVE
PAPER : BASICS OF CLINICAL RESEARCH MANAGEMENT
TIME : 3 HOURS MAX. MARKS: 100

SECTION – A

ANSWER ALL QUESTIONS (20 X 1=20)

1. Adverse Drug Reaction reporting is mandatory in clinical trials. A. True B. False
2. Mention the types of patents.
3. What is informed consent?
4. Define pharmaco-epidemology.
5. Expand CDER _____
6. Explain the Declaration of Helsinki.
7. Therapeutic Index is a measure of _____
8. FAERS stands for _____
9. List any 3 SOP.
10. Comment on Pharmacovigilance.
11. CMC stands for _____
12. List some special populations used in clinical trials.
13. In how many phase clinical research study is conducted?
    A. 5 B. 4 C. 8 D. 1
14. What is Bioequivalence?
15. Post marketing surveillance is _____
16. Comment on Single blind study.
17. Define null hypothesis.
18. Inspections in clinical trials are performed by _____
19. Explain quality assurance.
20. CDM stands for _____

SECTION – B

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

21. Describe the following:
    i) Patents ii) IRB iii) toxicological requirements
22. Explain in details the concept of clinical trials in special populations.
23. Write in brief on IND, NDA and ANDA applications of clinical research.
24. Write short notes on the process of drug discovery and development.
25. Enlist the principles of Nuremberg code and comment on GCP in labs.
26. Explain the significance of statistics in clinical research.
27. Discuss the European regulatory affairs in clinical research.

SECTION – C

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

28. Explain in detail the various aspects of pharmacokinetics and pharmacodynamics.
29. Discuss the regulations of Indian regulatory system Schedule Y for drug approval.
30. Give an account on history and stages of clinical trials.
31. Write the significance of clinical data management in clinical research.

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