STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted from the academic year 2015 – 2016 & thereafter)

SUBJECT CODE: 15BI/PC/CR44

M. Sc. DEGREE EXAMINATION, APRIL 2018
BIOINFORMATICS
FOURTH SEMESTER

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

SECTION – A

ANSWER ALL THE QUESTIONS IN A LINE OR TWO: (20X1=20 MARKS)

1. Adverse Reaction
2. Clinical Trial
3. CDER
4. Retrospective Study
5. Placebo Effect
6. Risk-Benefit Ratio
7. Single-Blind Study
8. Pharmacovigilance
9. Animal Studies
10. NDA
11. IND
12. European Regulatory system
13. FDA
14. Epidemiology
15. Meta-Analysis
16. Open-Label Trial
17. Pivotal Study
18. Medwatch
19. Declaration of Helsinki
20. eCRF

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SECTION – B

ANSWER ANY FOUR QUESTIONS. EACH ANSWER SHOULD NOT EXCEED 500 WORDS. All QUESTIONS CARRY EQUAL MARKS. DRAW DIAGRAMS WHEREVER NECESSARY (4X10=40 MARKS)

21. Brief the history of Clinical Trials.

22. Write a note on Pharmacokinetics and Pharmacodynamics.

23. Describe the significance of patent filing.

24. Write a note on post drug approval activities.

25. Explain the role of Ethics committee in clinical research.

26. Write a note on Nuremberg code and Declaration of Helsinki

27. How important is statistics in clinical research.

SECTION – C

ANSWER ANY TWO QUESTIONS. EACH ANSWER SHOULD NOT EXCEED1200 WORDS. All QUESTIONS CARRY EQUAL MARKS. DRAW DIAGRAMS WHEREVER NECESSARY (2X20=40 MARKS)

28. Explain the Schedule Y and its rules and regulations

29. What are the statistical considerations to be made in the design, analysis and reporting stage of clinical data?

30. Describe the different phases in clinical trials.

31. Explain a) SOP

    b) ICH-GCP

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