STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI 600 086

(For candidates admitted from the academic year 2010 - 11)

SUBJECT CODE: BI/PC/CR34

M. Sc. DEGREE EXAMINATION, NOVEMBER 2011
BIOINFORMATICS
THIRD SEMESTER

COURSE : CORE
PAPER : INTRODUCTION TO CLINICAL RESEARCH MANAGEMENT
TIME : 3 HOURS **MAX. MARKS: 100**

SECTION - A

ANSWER ALL THE QUESTIONS: **(20x1=20)**

1. No of Volunteers chosen in Phase I drug trial.
2. Pharmacokinetics:
3. Objective/s of Randomization studies in Drug trial.
4. Why Pharmacodynamics.
5. Objective/s of Bio-availability studies.
6. Define 'Informed consent'.
7. What is EDC?
8. Major role of "contract research organizations (CROs)".
9. PMS.
10. Major Objective of ANDA application.
11. Goals of NDA.
12. Objectives of Investigational New Drug (IND).
13. Efficiency of eCRF method.

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14. Major purpose of SOP (standard operating Procedure).
15. Why ADME test?
16. Why Pharmaco-vigilence.
17. Expand ICMR.
18. Why Data Validation?
19. Major advantage of online query management in CRM.
20. What is Risk-Assessment?

SECTION - B

ANSWER ANY FOUR THE QUESTIONS: **(10x4=40)**

21. What is Pharmaco Kinetic? Explain in brief.
22. What is the relevance of Statistical tools in clinical Studies?
23. What is Pharmacovigilance?
24. What is Pharmacodynamics.
25. Why is informed comment form important? Describe the procedure for different stoops.
26. What is SOP? Give a brief description.
27. What are the different levels of clinical trials?

SECTION - C

ANSWER ANY TWO QUESTIONS: **(20x2=40)**

28. Write an essay on Good Clinical Practices.
29. What is Schedule Y – Describe in brief?
30. Write a note on Roles of Ethics committee and Institutional Review board.
31. What is the relevance of SAE reconciliation and safety procedures in CRM?

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