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

SUBJECT CODE: 19BI/PE/CR15

M. Sc. DEGREE EXAMINATION, APRIL 2023
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. What are the documents mandatory to enroll in a clinical research study?
   a) Protocol b) Case Report Form
   c) Informed Consent Form d) Investigator's Brochure

2. A clinical research study is conducted in how many phases?
   a) 5 b) 4 c) 8 d) 1

3. To begin with a clinical research study, it is mandatory to get approval from?
   a) Sponsor b) Regulators and ethics committees both
   c) Regulator d) Both A and B correct

4. What is informed consent in a clinical trial?
   a) The subjects do not know which study treatment they receive
   b) Patients injected with placebo and active doses
   c) Fake treatment
   d) Signed document of the recruited patient for the clinical trial procedures

5. Which one of the following is the last step of a clinical trial process?
   a) Investigator selection b) Patient recruitment
   c) Statistical Analysis d) Data filed and registration

6. How many people will be selected for phase I trial?
   a) The whole market will be under surveillance b) 300-3000 people
   c) 20-300 people d) 20-50 people

7. Which one of the following will be checked under phase IV surveillance?
   a) The whole market will be under surveillance b) 300-3000 people
   c) 20-300 people d) 20-50 people

8. What do you mean by a randomized design?
   a) The subjects do not know which study treatment they receive
   b) Patients injected with placebo and active doses
   c) Randomly assigning subjects either for placebo or active dose
   d) Signed document of the recruited patient for the clinical trial procedures

9. Good Clinical Practice Guidelines covers:
   a) quality and integrity of study data and results
   b) contents of the regulatory files System
   c) Rights, safety and welfare of research participants
   d). all of the above

10. The PI should promptly notify the IRB if protocol deviations are uncovered by the monitoring of the study and what the corrective action plan is
    a) True b)False

11. Quality Control (QC) of study data should occur:
    a) on a random basis by an auditor
    b) on a regular basis by the study team
    c) on a pre-determined basis by the IC QA monitor System
    d) should take place on a irrregular basis.

12 .Regulatory files are not only for use by the research team, they may be inspected by monitoring entities.
    a) True b) False

13. Some elements of a DMP include:
    a. A corrective and preventative action (CAPA) plan System:
    b. Definition of source documentation and Case Report Forms (CRFs)
    c. Plan for QC/QI of raw and transformed data
    d. b and c

14. Some elements of Data Quality Management (DQM) include establishing a Data Monitoring Plan (DMP) in the protocol and maintaining the regulatory file.
    a) True b)False

15. Which of the following is NOT associated with Phase 1 clinical trials?
    a) ~ 100 participants b) Patients with target disease
    c) Establishment of safety of drug in humans d)Establishment of normal human dosage

16. Which of the following is NOT associated with Phase 2 clinical trials?
    a) Patients with target condition b) Placebo-controlled trial
    c) Monitoring of side effects d)Thousands of participants

17. Which of the following sources does NOT provide Individual Case Safety Reports (ICSRs)?
    a) Pharmaceutical companies incorrect
    b) Clinical Research Organizations incorrect
    c) Individual patients
    d) Regulatory agencies

18. Which of the following is NOT one of the principles of Good Clinical Practice (GCP)?
    a) The well-being of subjects is of highest priority.
    b) Trials should have a clear, defined protocol.
    c) Informed consent of subjects must be obtained.
    d) The protocol is approved by the trial organization.

19. Which one of the following describes “double dummy”?
    a) The subjects do not know which study treatment they receive
    b) Patients injected with placebo and active doses
    c) Fake treatment
    d) Signed document of the recruited patient for the clinical trial procedures

20. Which one of the following is the last step of a clinical trial process?
    a) Investigator selection b) Patient recruitment
    c) Statistical Analysis d) Data filed and registration

SECTION – B

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

21. Demonstrate in details about Pharmacokinetics and pharmacodynamics
22. Summarize various databases available for drug search
23. What is Pharmaco-epidemiology? Write its importance in Clinical research.
24. Elaborate salient features of European Regulatory Affairs
25. Discuss the roles and responsibilities of clinical research professionals
26. Explain in detail about the Importance of CDM in clinical research,
27. Examine the role of Ethics Committees and Institutional review boards on 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. Define Clinical trials. Outline the history of clinical trials and demonstrate the stages of clinical trials
29. Describe the role of INDIAN Regulatory system in Clinical Research
30. Compile the salient features Clinical trial Project Management
31. Write in details about the emerging technologies in Drug Discovery

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