STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted from the academic year 2023 – 2024 & thereafter)

M. Sc. DEGREE EXAMINATION, APRIL 2026
BIOINFORMATICS
FOURTH SEMESTER

COURSE : ELECTIVE
PAPER : CLINICAL RESEARCH MANAGEMENT
SUBJECT CODE : 23BI/PE/CR15
TIME : 3 HOURS MAX. MARKS: 100

Q. No.	SECTION A All questions to be answered (10 x 1=10 marks)	CO	KL
1	Ephedrine used for asthma treatment is derived from ____ a. Foxglove b. Mahuang c. Cinchona d. Willow bark	CO1	K1
2	Henbane was described as an anti-venom for snakebites by _____ a. Hippocrates b. Galen c. Susruta d. Avicenna	CO1	K1
3	Apomorphine is an example of ____ a. Synthetic drugs b. Semi-synthetic drugs c. Natural drugs d. Mineral drugs	CO1	K1
4	Graph neural networks are used in drug discovery to ___ a. Store drug data b. predict drug-target interaction c. Manufacture drugs d. Perform clinical trials	CO1	K1
5	____ is an intentional deception made for personal gain. a. Misconduct b. Fraud c. Plagiarism d. Fabrication	CO1	K1
6	Clinical research mainly involves a. Studying plat metabolism b. Research conducted on human subjects c. Soil microbial studies d. Animal taxonomy	CO2	K2
7	Which committee is responsible for protecting the rights of the participants? a. Ethics committee b. Research committee c. Institutional review board d. Inspection committee	CO2	K2
8	Phase I clinical trials mainly evaluate ____ a. Toxicity b. Drug efficacy and side effects c. Market approval d. Drug packaging	CO2	K2
9	The document that describes the objectives, design and methodology of a clinical trial is called ____ a. Trial protocol b. Case report form c. Consent form d. Audit report	CO2	K2
10	Randomization in clinical trials helps to ____ a. Increase drug price b. Reduce bias c. Reduce sample size d. Reduce side effects	CO2	K2
Q. No.	**SECTION B** **Answers in about 50 words (10 x 2= 20 marks)**	**CO**	**KL**
11	State the role of ICH guidelines in regulatory harmonization?	CO3	K3
12	List the good clinical practices.	CO3	K3
13	Mention two professionals involved in drug discovery and their regulatory roles?	CO3	K3
14	Identify two factors affecting drug absorption?	CO3	K3
15	Differentiate between NDA and ANDA in regulatory submissions	CO3	K3

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16	Examine the role of Schedule Y in ensuring ethical clinical trials in India?	CO4	K4
17	How does age stratification improve data interpretation in elderly populations?	CO4	K4
18	Why is data transparency important in preventing research misconduct?	CO4	K4
19	Differentiate between paper CRF and e-CRF in terms of data quality and efficiency?	CO4	K4
20	Mention the role of Quality Assurance in clinical data management?	CO4	K4
Q. No.	**SECTION C** **Answer in about 600 words (4 x 10= 40 marks)**	**CO**	**KL**
21	a) Examine the importance of pharmaco-epidemiology in clinical research and analyze its role in post-marketing surveillance? **(OR)** b) Analyze the relationship between clinical trial phases used to evaluate drug safety, efficacy and risk-benefit ratio?	CO4	K4
22	a) Examine the importance of drug databases such as PubChem, DrugBank in drug research? **(OR)** b) Evaluate the pharmacokinetic and toxicological requirements in drug design.	CO4	K4
23	a) Assess the structure and functions of European Medicines Agency and evaluate its role in drug regulation in Europe? **(OR)** b) Evaluate the importance of post-marketing surveillance (PMS) in identifying adverse drug reaction?	CO5	K5
24	a) Analyze the role of Informed Consent Form in clinical research and evaluate how it protects participant rights? **(OR)** b) Critically evaluate the importance of SAE reconciliation.	CO5	K5
Q. No.	**SECTION D** **Answer any TWO questions in about 1200 words (2x 15=30 marks)**	**CO**	**KL**
25	Critically evaluate the ethical principles outlined in the Nuremberg Code and discuss their relevance in present-day clinical research	CO5	K6
26	Design a regulatory compliance strategy based on Schedule Y to conduct clinical trials in India?	CO5	K6
27	Develop a standard operating procedure (SOP) for clinical trial conduct and justify its importance in ensuring quality and regulatory compliance?	CO5	K6
28	Create a data validation and quality assurance framework to minimize errors and ensure high-quality clinical trial data.	CO5	K6

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