TOTAL PAGES : 2

22BTU524BN

PSG COLLEGE OF ARTS & SCIENCE
(AUTONOMOUS)

BSc DEGREE EXAMINATION DECEMBER 2025
(Fifth Semester)

Branch - **BIOTECHNOLOGY**

MAJOR ELECTIVE COURSE – I : CLINICAL TRIAL MANAGEMENT

Time: Three Hours Maximum: 75 Marks

SECTION-A (10 Marks)
Answer **ALL** questions
ALL questions carry **EQUAL** marks (10 × 1 = 10)

Module No.	Question No.	Question	K Level	CO
1	1	Recall the completed year of human genome project. a) 1990 b) 2001 c) 2003 d) 2005	K1	CO1
	2	The principle of transplantation is based on _____. a) Genetic drift b)Immune compatibility c) Enzyme activity d) Hormonal balance	K2	CO1
2	3	Which of the following is an information research activity? a) Clinical trial documentation b) Patent landscaping c) Literature review d) All of the above	K1	CO2
	4	How the clinical trials phases are classified ? a) Phases I-IV b) Only Phase I c) Pre-trials and post-trials d) None	K2	CO2
3	5	Who will provide Informed consent ? a) Sponsor b) Trial participants c) CRO d)Ethics commitee	K1	CO3
	6	Which one will ensure Good Clinical practices ? a) Ethical and scientific quality b) Sponsor profits c) Only regulatory approval d) Marketing advantages	K2	CO3
4	7	Select the correct option related to Medical coding from the following a) Entertainment purpose b) Insurance claims and healthcare records c) Tax collection d) Patient admission only	K1	CO4
	8	The CPT stands for _____. a) Current Payment Technology b) Current Procedure Terminology c) Clinical Patient Treatment d) Clinical Payment Tracker	K2	CO4
5	9	Who will issue the CPC certification? a) AAPC b) WHO c) FDA d) AMA	K1	CO5
	10	Why the BPO Companies mainly hire medical coders? a) International insurance claim processing b) Local hospital management only c) Teaching in medical schools d) Pharmacy marketing	K2	CO5

Cont...

SECTION - B (35 Marks)

Answer **ALL** questions

ALL questions carry **EQUAL** Marks (5 × 7 = 35)

Module No.	Question No.	Question	K Level	CO
1	11.a.	Explain the main goals of the human genome project.	K2	CO1
		(OR)		
	11.b.	Illustrate the importance of chemical evaluation guidelines in drug development.		
2	12.a.	Demonstrate the Phase I trial procedure.	K2	CO2
		(OR)		
	12.b.	Infer the ethics in contract research.		
3	13.a.	Write the short note on importance of blinding in clinical trials.	K3	CO3
		(OR)		
	13.b.	Identify the process of protocol approval.		
4	14.a.	Write a note on CPT coding system.	K3	CO4
		(OR)		
	14.b.	Enlist the significance of HIPAA in patient privacy?		
5	15.a.	Classify the career opportunities for CPC certified coders.	K4	CO5
		(OR)		
	15.b.	Explain about Medical transcription in brief.		

SECTION -C (30 Marks)

Answer **ANY THREE** questions

ALL questions carry **EQUAL** Marks (3 × 10 = 30)

Module No.	Question No.	Question	K Level	CO
1	16	Categorize the ethical guidelines for biomedical research with examples.	K4	CO1
2	17	Examine the Good Laboratory Practices (GLP) and Good Clinical Practice (GCP) in Contract research.	K4	CO2
3	18	Appraise the four stages of clinical trials with examples.	K5	CO3
4	19	Assess the process of medical coding and billing with examples.	K5	CO4
5	20	Formulate the HCPCS coding system in detail with examples.	K6	CO5

Z-Z-Z END