Name: **Enrolment No:**	

UPES

End Semester Examination, May 2025

Course: Emerging Technologies in Clinical Trials **Semester: VI**

Program: Integrated (B. Sc.) - (M. Sc.) Clinical Research **Duration: 3 Hours**

Course Code: HSCR3019 **Max. Marks: 100**

Instructions: Attempt all the Sections

S. No.	Section A **Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)**	Marks	COs
Q 1	Which pharmaceutical company has first introduced an FDA-approved ingestible biosensor for medication adherence? a) Pfizer b) Proteus Digital Health c) Johnson & Johnson d) Novartis	**1.5**	**CO1**
Q 2	How does Natural Language Processing (NLP) contribute to clinical trial automation? a) By analyzing and extracting insights from clinical trial documents b) By manually reviewing patient records c) By slowing down trial workflows d) By eliminating the need for electronic data capture	**1.5**	**CO2**
Q 3	Which trend is helping businesses make real-time decisions using large sets of data? A. Cybersecurity threats B. Big Data and Analytics C. Offline marketing D. Paper-based documentation	**1.5**	**CO1**
Q 4	…… is one of the key reasons organizations adopt automation technologies. A. To increase manual labor B. To reduce productivity C. To streamline operations and reduce human error D. To eliminate all forms of digital communication	**1.5**	**CO2**
Q 5	Which automated technology helps in remote monitoring of patients in clinical trials? a) Paper-based case report forms	**1.5**	**CO3**

	b) Electronic Health Records (EHR) c) Wearable biosensors d) Manual patient logs		
Q 6	**True or False:** Implementing automation can help pharmaceutical companies shorten drug development cycles**.**	**1.5**	**CO1**
Q 7	**True or False:** A potential concern with ingestible sensors is ensuring patient consent and data privacy.	**1.5**	**CO2**
Q 8	**True or False:** Virtual clinical trials limit patient access due to centralized site requirements.	**1.5**	**CO3**
Q 9	What is the benefit of incorporating patient input during the trial design phase? A. Reduced data accuracy B. Increased regulatory burden C. Improved protocol adherence and relevance D. Decreased trial enrollment	**1.5**	**CO1**
Q 10	**True or False:** Artificial Intelligence has no impact on patient recruitment in clinical trials.	**1.5**	**CO2**
Q 11	**True or False:** Big data analytics reduce trial efficiency and increase manual effort.	**1.5**	**CO1**
Q 12	**True or False:** Blockchain is primarily used to replace artificial intelligence in healthcare.	**1.5**	**CO2**
Q 13	Patient engagement platforms aim to: A. Increase patient dropout B. Promote confusion about trial participation C. Empower and inform patients during trials D. Avoid digital interactions	**1.5**	**CO3**
Q 14	Which of the following tools is commonly used for patient engagement? A. Sticky notes B. Interactive mobile apps C. Carbon copy paper D. Loudspeakers	**1.5**	**CO2**
Q 15	**True or False:** Automated payment solutions improve speed and transparency of payments.	**1.5**	**CO1**
Q 16	Which of the following is a key application of ingestible biosensors in healthcare? a) Enhancing food digestion b) Tracking medication adherence c) Replacing all wearable devices d) Monitoring mental health only	**1.5**	**CO1**
Q 17	Which organ in the human body has the highest natural regenerative capacity? a) Heart b) Liver c) Brain d) Lungs	**1.5**	**CO2**

Q 18	Which of the following technologies is widely used for automating regulatory compliance in clinical trials? a) Cloud-based platforms b) Handwritten reports c) Paper-based submission systems d) Fax machines	**1.5**	**CO3**
Q 19	**True or False:** Integrated and automated systems can streamline participant reimbursements.	**1.5**	**CO1**
Q 20	How can ingestible biosensors improve patient outcomes in clinical trials? a) By tracking drug absorption and metabolism in real time b) By replacing all clinical trials with AI-based models c) By eliminating the need for human subjects d) By reducing trial duration without data collection	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
Q 1	Discuss how blockchain ensures data security and integrity in clinical trials.	**5**	**CO1**
Q 2	Explain the working mechanism of ingestible biosensors and their applications in healthcare.	**5**	**CO2**
Q 3	Evaluate the role of digital health technologies (e.g., wearable devices, ingestible sensors) in transforming patient-centered healthcare.	**5**	**CO3**
Q 4	Describe the role of AI and robotics in accelerating drug discovery and trial phases.	**5**	**CO2**
Section C (2Qx15M=30 Marks)			
Q 1	**Scenario:** A pharmaceutical company is conducting a clinical trial to evaluate a new cardiovascular drug aimed at lowering the risk of heart failure in patients with hypertension. The trial incorporates digital biomarkers such as heart rate variability, electrocardiogram data, and continuous blood pressure monitoring through wearable devices. These digital biomarkers are integrated with a mobile app that tracks real-time patient health data. Questions: a) Define digital biomarkers and explain their role in clinical trials. (5 marks) b) Explain the benefits and challenges of using digital biomarkers for real-time patient monitoring in clinical trials. (5 marks) c) Discuss the ethical considerations related to the collection, storage, and use of digital biomarkers in clinical trials. (5 marks)	**15**	**CO4**
Q 2	**Scenario:** A healthcare startup is developing a clinical trial for children aged 7–12 diagnosed with attention deficit hyperactivity disorder (ADHD). The trial uses a videogame-based platform in three different capacities: 1. As a computer-assisted intervention tool to reinforce behavioral therapy.	**15**	**CO5**

	2. As a primary intervention tool, where the game mechanics are specifically designed to improve attention span and impulse control. 3. As a cognitive rehabilitation method, to enhance executive functioning through repetitive, engaging tasks targeting memory and processing speed. The trial aims to evaluate the effectiveness, engagement level, and cognitive outcomes compared to traditional therapy approaches. Questions: a) Explain the difference between computer-assisted tools, primary intervention tools, and cognitive rehabilitation methods in clinical trials. (5 marks) b) Discuss the important design elements used in videogames as primary therapeutic intervention for ADHD. (5 marks) **c)** Evaluate the potential of videogame-based tools to be used in future trials beyond ADHD. (5 marks)		
Section D **(2Qx10M=20 Marks)**			
Q 1	Define digital biomarkers and explain their role in clinical trials, particularly for cardiovascular diseases like hypertension and heart failure.	**3+7**	**CO3**
Q 2	Discuss the ethical considerations associated with using EMA in clinical trials, including privacy concerns and data security.	**10**	**CO4**