| | |
|---|---|
| **Name:**<br>**Enrolment No:** | UPES<br>UNIVERSITY WITH A PURPOSE |

**UNIVERSITY OF PETROLEUM AND ENERGY STUDIES**
**School of Health Sciences**

**End Semester Examination, December 2021**

**Programme Name: M.Sc Clinical Research** **Semester : I**
**Course Name : Management of Clinical Trials** **Time : 3 hrs**
**Course Code : HSCR7004** **Max. Marks : 100**
**Instructions : Attempt all the Sections**

## SECTION A

| | | Marks | |
|---|---|---|---|
| **Ques** | **MCQs, One or two line answers, True/False, Fill in the blanks** | **30** | **CO1** |
| 1 | What is an Interventional study? | **1.5** | **CO1** |
| 2 | Define Phase 0 clinical trial. | **1.5** | **CO2** |
| 3 | Who is responsible for preparing essential documents like protocol/ investigators brochure/ informed consent form/ case report form during clinical trials?<br>a. Investigator<br>b. Ethics committee<br>c. Scientist<br>d. Sponsor | **1.5** | **CO3** |
| 4 | Mention three non-clinical evaluations tests, conducted for life threatening diseases. | **1.5** | **CO1** |
| 5 | Why Paediatric trials are more challenging to conduct, than the trials conducted in adults? | **1.5** | **CO2** |
| 6 | Define “Surrogate end point”. | **1.5** | **CO3** |
| 7 | What is “Red Flag” in clinical trials? | **1.5** | **CO1** |
| 8 | What is the purpose of “Investigator’s Brochure” document? | **1.5** | **CO2** |
| 9 | Sponsor responsibilities include……..<br>a. Design Study<br>b. Manage Study<br>c. Audit Study<br>d. All of the above | **1.5** | **CO3** |
| 10 | Clinical Data Management begins with-<br>a) Development of informed consent form<br>b) Development of clinical trial insurance<br>c) Development of investigator’s brochure | **1.5** | **CO1** |

| | | | |
|---|---|---|---|
| | d) Development of data management plan and case report form | | |
| 11 | Case report form should include-<br>a) Database structure specification<br>b) SOP for data management processes<br>c) Description of how data will be reviewed<br>d) None of the above | **1.5** | **CO2** |
| 12 | Role of clinical data coordinator is:<br>a) Coding adverse event, medical history<br>b) Create database and edit check<br>c) Design crf<br>d) Tracking receipt of crf pages | **1.5** | **CO3** |
| 13 | What is the function of ICH-GCP? | **1.5** | **CO1** |
| 14 | What is "Single Blind" study? | **1.5** | **CO2** |
| 15 | In target identification, a good target needs to be efficacious, safe, meet clinical and commercial needs and, above all, be…… | **1.5** | **CO3** |
| 16 | …… is the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs. | **1.5** | **CO1** |
| 17 | Define the term "Adverse Drug Reaction". | **1.5** | **CO2** |
| 18 | Mention any two methods of target validation in drug discovery. | **1.5** | **CO3** |
| 19 | **True or False**<br>"In first pass metabolism, after absorption, drug is transported via the portal circulation to the liver, where they are metabolised extensively (more than 90–95%). This results in a marked reduction in systemic bioavailability". | **1.5** | **CO1** |
| 20 | Give any two example of translational medicine. | **1.5** | **CO2** |
| **SECTION B** | | | |
| | **Short Answer type Questions (5 marks each)** | **20** | **CO** |
| 1 | Explain with two examples the function of surrogate end points in clinical trials. | **2.5+2.5** | **CO1** |
| 2 | Discuss "Translational Research Model". | **5** | **CO2** |
| 3 | Mention the age-related physiological changes that may affect drug distribution process in geriatric population. | **5** | **CO3** |
| 4 | Distinguish between interventional and non-interventional study in clinical trials (any two difference). | **2.5+2.5** | **CO4** |
| **SECTION C** | | | |
| | **Case Studies** | **30** | |
| 1 | A rheumatologist developed a monoclonal Ab that he believe is likely to be effective in RA treatment, and it has successfully moved through Phase 1 & 2 tests. In designing a Phase 3 RCT, comparing to placebo treatment,<br>Ques 1. What is the primary focus of Phase 3 clinical trial in this study? (5 marks) | **15** | **CO4** |

| | | | |
|---|---|---|---|
| | Ques 2. What is Placebo treatment? (2 marks)<br>Ques 3. What is the significance of Phase 3 studies of a new drug development process? (5 marks )<br>Ques 4. Why do Phase 3 trials fails in most of the clinical trials ? (3 marks) | | |
| 2 | What is Site Management Operations in Clinical Trials? (2 marks)<br>What is the difference between SMO and CRO? (3 marks)<br>Discuss the functions of SMO? (5 marks)<br>Discuss the role and responsibilities of sponsor and investigator in clinical trial. (5 marks) | **15** | **CO5** |
| **SECTION D** | | | |
| | **Long Answer type Questions Scan and Upload (10 marks each) For 10 marks word limit not more than 300 words** | **20 marks** | |
| 1 | Discuss the important stages of drug development process?<br>**OR**<br>Discuss in detail about study design and conduct of paediatric trials. | **10** | **CO1 CO5** |
| 2 | What is CRF? Discuss the guidelines related to CRF filling Research ethics and research audits. (2+8 marks) | **10** | **CO2 CO3** |
| | | | |