| Name:<br>Enrolment No: | UPES<br>UNIVERSITY OF TOMORROW |
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**UPES**

**End Semester Examination, December 2024**

**Course: Medical Writing** **Semester: VII**
**Program: INT. B.Sc. M.Sc. Clinical Research** **Time : 03 hrs.**
**Course Code: HSCC8010** **Max. Marks: 100**

**Instructions: Attempt all the questions**

| S. No. | Section A<br>(20Qx1.5M= 30 Marks) | Marks | COs |
|---|---|---|---|
| 1. | Which of the following documents is regarding patient voluntariness to participate in a clinical trial?<br>a) case report form b) informed consent form<br>b) investigator's brochure d) confidentiality agreement | 1.5 | CO1 |
| 2. | Name any **TWO** ethics principle laid down by ICMR in 2006. | 1.5 | CO1 |
| 3. | List any **THREE** essential requirement of good research data. | 1.5 | CO1 |
| 4. | The_____ in a clinical trial system is the person who initiates, funds and organizes a clinical trial. | 1.5 | CO1 |
| 5. | State the significance of medical writing. | 1.5 | CO2 |
| 6. | The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported smoothly is regulated by a _____. | 1.5 | CO2 |
| 7. | Define vetting of advertisements. | 1.5 | CO2 |
| 8. | Write benefits of electronic data capture method. | 1.5 | CO2 |
| 9 | State any **THREE** differences between primary and secondary data. | 1.5 | CO3 |
| 10. | Enlist any **THREE** major challenges in medical writing. | 1.5 | CO3 |
| 11. | CTD is _____. | 1.5 | CO3 |
| 12. | Write the full form of ICH and mention founder countries. | 1.5 | CO3 |
| 13. | Which of the following steps are involved in site qualification of a clinical trial?<br>a) agreement with sponsor b) potential PI feasibility<br>c) pharmacovigilance d) monitoring visit | 1.5 | CO4 |
| 14. | Write any **THREE** characteristics of a good table. | 1.5 | CO4 |
| 15. | State **THREE** advantages of medical writing. | 1.5 | CO4 |

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| 16. | The _____is the person responsible, individually or as a leader, for the conduct of a clinical trial at the particular site. | 1.5 | CO4 |
| 17. | Define scientific integrity. | 1.5 | CO5 |
| 18. | Enlist essentials of public advertising. | 1.5 | CO5 |
| 19. | State the importance of an effective SOP. | 1.5 | CO5 |
| 20. | List any three differences between audit and investigation. | 1.5 | CO5 |
| | **Section B**<br>**(4Qx5M=20 Marks)** | | |
| 1. | Write a note on technical issues in medical writing. | 5 | CO1 |
| 2. | Describe objectives, advantages, and limitations of medical writing. | 5 | CO2 |
| 3. | Discuss the essential features of an effective SOP. | 5 | CO3 |
| 4. | Describe role of data management in clinical drug trials. | 5 | CO4 |
| | **Section C**<br>**(2Qx15M=30 Marks)** | | |
| 1. | **Background:**<br>Considering implementing a quality system for practice and to interpret readings. Prepare a SOP for any medical device. | 15 | CO2 |
| 2. | **Background:**<br>• The prevalence of breast cancer has increased in your country over the last 5 years.<br>• You want to examine the association between contraceptives intake and breast cancer risk.<br>• You have limited time and funding to conduct this study.<br>Propose the requirements for training the team members and write a brief advertisement. | 15 | CO5 |
| | **Section D**<br>**(2Qx10M=20 Marks)** | | |
| 3. | Write a detailed note on CTD. | 10 | CO3 |
| 4. | Discuss in detail the set up for collection and delivery of unbiased, concise, and comprehensive scientific data. | 10 | CO2 |