Reg. No. \_\_\_\_\_\_\_\_\_\_\_\_



**End Semester Examination – Nov / Dec – 2019,**

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|  |  |  |  |
| **Code :** | **14BI2031** | **Duration :** | **3hrs** |
| **Sub. Name :** | **CLINICAL DATABASE MANAGEMENT** | **Max. Marks :** | **100** |

**ANSWER ALL QUESTIONS (5 x 20 = 100 Marks)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Q. No.** |  | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. |  | Explain Clinical Database Management process overview with example. | CO2 | 20 |
| **(OR)** | | | | |
| 2. |  | Justify the statement “Clinical trials are real world applications of the scientific methods” with example. | CO2 | 20 |
|  |  |  |  |  |
| 3. |  | Describe the creation procedure and the Case Report Form (CRF) design. | CO1 | 20 |
| **(OR)** | | | | |
| 4. |  | Explain in detail about the Quality Assurance (QA) and Quality Check (QC) in managing the clinical data. | CO1 | 20 |
|  |  |  |  |  |
| 5. |  | Describe International Non Proprietary Names (INN) and Anatomical-Therapeutic-Chemical (ATC) for the medicine with example. | CO3 | 20 |
| **(OR)** | | | | |
| 6. |  | Write in detail the process and procedure workflow in different phases of clinical trials. | CO3 | 20 |
|  |  |  |  |  |
| 7. |  | **Describe the process to identify Adverse Event (AE) and Severe Adeverse Event (SAE) in clinical research.** | CO1 | 20 |
| **(OR)** | | | | |
| 8. |  | Write a note on three tools for accessing the WHO-DD. | CO2 | 20 |
|  | | **Compulsory**: |  |  |
| 9. |  | Write in detail the Good Clinical Laboratory Practice (GCLP) standards with example. | CO3 | 20 |