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



**End Semester Examination – Nov/Dec – 2017**

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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.** | **Sub Div.** | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. |  | Describe CRF and its types. Develop atleast one CRF for Physical Examination to test a cancer drug. | CO1 | 20 |
| (OR) | | | | |
| 2. |  | Explain the do’s and don’ts to be exercised while designing a CRF form. | CO1 | 20 |
|  |  |  |  |  |
| 3. |  | Describe and the types of adverse events observed during clinical trials and steps taken thereafter. | CO1 | 20 |
| (OR) | | | | |
| 4. |  | Describe how and why Standard Operating Procedures are written for Clinical Trials. | CO1 | 20 |
|  |  |  |  |  |
| 5. |  | Illustrate the workflow of a Clinical Data Management Process. | CO2 | 20 |
| (OR) | | | | |
| 6. |  | Explain the role of the Committee for Proprietary Medicinal Products. | CO2 | 20 |
|  |  |  |  |  |
| 7. |  | Define medical coding process and describe its various applications. | CO2 | 20 |
| (OR) | | | | |
| 8. | a. | Define IND and its types. | CO2 | 10 |
|  | b. | Describe the process of IND Application. | CO2 | 10 |
|  | |  |  |  |
|  | | **Compulsory**: |  |  |
| 9. |  | Describe historical events relating to drug related adverse effects that led to Pharmacovigilance and the formation of the FDA. | CO3 | 20 |

ALL THE BEST