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



**UNIVERSITY**

(Karunya Institute of Technology & Sciences)

(Declared as Deemed-to-be University under Sec.3 of the UGC Act, 1956)

**End Semester Examination – Nov/Dec – 2016**

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|  |  | **Semester :** | **2016-17 ODD** |
| **Code :** | **14BI2031** | **Duration :** | **3hrs** |
| **Sub. Name :** | **CLINICAL DATABASE MANAGAEMENT** | **Max. marks :** | **100** |

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

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| **Q. No.** | **Sub Div.** | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. |  | Explain the role of the Committee for Proprietary Medicinal Products | CO1 | 20 |
| (OR) | | | | |
| 2. |  | Define a CRF and its types. Develop atleast one CRF for Inclusion and Exclusion criteria for any disease. | CO1 | 20 |
| 3. |  | Describe the format and content of ANDA. | CO1 | 20 |
| (OR) | | | | |
| 4. |  | Explain the need for animal studies and the parameters that are checked before human trials. | CO1 | 20 |
| 5. |  | Describe the various drug related adverse events that led to Pharmacovigilance and FDA. | CO2 | 20 |
| (OR) | | | | |
| 6. |  | Explain the do’s and don’ts while designing a CRF form. | CO2 | 20 |
| 7. |  | Illustrate the drug regulatory structure in India and its states. | CO2 |  |
| (OR) | | | | |
| 8. | a. | Describe adverse events and the types of adverse events observed during clinical trials. | CO2 | 10 |
|  | b. | Design a CRF form to report Adverse events in a clinical trial. | CO2 | 10 |
|  | | **Compulsory:** |  |  |
| 9. | a. | Using a flowchart describe the workflow of CDM and define the responsibilities of a CDM team. | CO2 | 20 |

ALL THE BEST