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 – April/May – 2017**

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| **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. |  | Describethe functions of the Committee for Proprietary Medicinal Products. | CO1 | 20 |
| (OR) | | | | |
| 2. |  | Define the contents of a CRF and the types of forms required for a trial. | CO1 | 20 |
| 3. |  | Describe the format and content of ANDA. | CO1 | 20 |
| (OR) | | | | |
| 4. |  | Explain the types ofinvitro studiesconducted on animals before Phase I human trials. | CO1 | 20 |
| 5. |  | Describe the various drug related adverse events that led to Pharmacovigilance and the formation of the FDA. | CO2 | 20 |
| (OR) | | | | |
| 6. |  | Describe any two tool used for Electronic Data Capture of Clinical Data. | CO2 | 20 |
| 7. |  | Illustrate the drug regulatory structure in India and its states. | CO2 | 20 |
| (OR) | | | | |
| 8. | a. | Describe the process of medical billing and coding procedures required in a hospital. | CO2 | 10 |
|  | b. | Design a CRF – Physical Examination form for testing a medical device. | CO2 | 10 |
|  | | **Compulsory:** |  |  |
| 9. |  | Discuss the Do’s and Don’ts while designing a CRF form with suitable examples. | CO2 | 20 |

ALL THE BEST