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



**UNIVERSITY**

(Karunya Institute of Technology & Sciences)

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

**Supplementary Examination – June – 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. |  | Elucidate the Clinical Data Management Process mentioning members of the CDM team. | CO1 | 20 |
| (OR) | | | | |
| 2. |  | Describe how Standard Operating Procedures are written for the recruitment of volunteers to a trial. | CO1 | 20 |
|  |  |  |  |  |
| 3. |  | Describe drug regulatory procedures in India. | CO1 | 20 |
| (OR) | | | | |
| 4. |  | Discuss “Electronic Data Capture as a tool for CDM”. | CO1 | 20 |
|  |  |  |  |  |
| 5. | a. | Illustrate the workflow of a clinical trial. | CO1 | 10 |
|  | b. | Describe phases I and II of a clinical trial for a drug. |  | 10 |
| (OR) | | | | |
| 6. | a. | Define IND and the criteria for an IND. | CO2 | 10 |
|  | b. | Describe the process of IND Application. | CO2 | 10 |
|  |  |  |  |  |
| 7. |  | Describe medical coding, the types of codes and their applications. | CO2 | 20 |
| (OR) | | | | |
| 8. |  | Design a Serious Adverse Event CRF for a anti-diabetic drug trial. | CO2 | 20 |
|  | |  |  |  |
|  | | **Compulsory**: |  |  |
| 9. |  | Explain the history and the magnitude of Pharmacovigilance in the drug industry. | CO2 | 20 |

ALL THE BEST