

**Jamia Hamdard**  
**Centre for Translational & Clinical Research**  
**M.Sc. in Clinical Research Semester III**  
**Semester Examination – December 2023**  
**Paper Code – MCR DSE301; Paper Title: CT Operations**

Time : 1 hour 15 minutes

Total Marks: 30

*Write the roll number at the top immediately on receipt of this question paper. Attempt all questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples whenever necessary*

**SECTION A [10 MARKS]**

- 1. Answer all the following questions regarding in CT Operations:** **[1x10=10]**
- a) The most important contribution of a sponsor is \_\_\_\_\_.
  - b) The most important consideration in selecting a clinical trial site is \_\_\_\_\_.
  - c) The most important objective for conducting an Investigator's Meeting is \_\_\_\_\_.
  - d) Role of Biostatistician in developing a protocol involves \_\_\_\_\_.
  - e) CT supplies are released only after \_\_\_\_\_.
  - f) The most important objective of the site initiation visit is \_\_\_\_\_.
  - g) The most important objective of an interim monitoring visit is \_\_\_\_\_.
  - h) Role of Data Safety Monitoring Board during a clinical trial involves \_\_\_\_\_.
  - i) The number of queries during data management reflects \_\_\_\_\_.
  - j) The most important objective of a trial close-out visit is \_\_\_\_\_.

**SECTION B [12 MARKS]**

- 2. Answer any 3 (three) of the following:** **[4X3=12]**
- a) Clinical Trial Management Committee.
  - b) Vendor management during a clinical trial.
  - c) CT Monitoring Plan.
  - d) Handling of Missing data.
  - e) Clinical Study Report – their formats and objectives.

**SECTION C [08 MARKS]**

- 3. Answer any 1 (ONE) of the following:** **[8x1=8]**
- a) During the conduct of a clinical trial evaluating the efficacy of dapagliflozin, a SGLT-2 inhibitor in patients with compensated heart failure, two patients of a particular trial site were hospitalized with fever and pus cells in the urine. Discuss the next steps that are required to be undertaken by the stakeholders involved.
  - b) Anemia in pregnancy is very common in Nepal. The Ministry of Health initiated to evaluate a new formulation of iron comparing it to standard formulation in 800 pregnant patients with anemia. The objective of the clinical trial was to assess if the new formulation could improve the Apgar Score at birth in the treated population. Unfortunately an earthquake of intensity 7.0 on the Richter scale struck the Himalayan nation during the conduct of the trial. As a clinical trial coordinator working at the epicenter of the earthquake, discuss the steps that are required to be undertaken in the short and medium term.