

End Semester Examinations - 2015-16 Even Semester - May 2016

14BI2031 Clinical Database Management

Set B

Time : 3 hrs
Total Marks: 100

1. Explain the need for data safety and database closure in clinical trials.
OR
 2. Define the members of a CDM team. Describe the responsibilities of every member of the team.
 3. Create a sample CRF to indicate the spread of Cholera in an Indian State.
OR
 4. Describe some of the important organizations involved in drug safety monitoring across the world.
 5. Explain the need for Preclinical Studies in a clinical trial.
OR
 6. Describe database design and build for a clinical trial site.
 7. Explain how data is validated and data queries solved.
OR
 8. Define atleast 10 common terms used in the language of clinical trials.
 9. Describe the history of Pharmacovigilance that led to stricter regulations for drug safety.
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Wishing you All the Best
