

Exam Date & Time: 11-Mar-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.(March 2022)

Clinical Research Regulations [PQA-MRA103T - S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) Analyse critically the regulatory guidance of FDA on Phase II clinical trials. What are the types of "End of Phase II meetings?" (10)
- 2) Compare the regulatory requirements of "Traditional IND application" and "Exploratory IND application". (10)
- 3) Explain the objectives of Institutional Review Board in brief. (10)
- 4) Why choice of control groups is important? Analyse the types of control groups with their advantages and disadvantages. (10)
- 5) Compare and analyse critically the content requirements of NDA and ANDA. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) Explain the best practices for special populations in clinical research. (5)
- 7) What IMDRA will regulate? (5)
- 8) What are the guiding principles of GCP? (5)

- 9) Critically analyse the design considerations for clinical trials as per ICH E8. (5)
- 10) What are the methods of summarizing clinical trial data through simple descriptive statistics? (5)

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