2/17

0906E550

Candidate's Seat No :_____

PG Dip. CTM Examination
PGD in Clinical Trial Management
June 2022

Time : 2-00 Hours] **[Max. Marks : 50**

Instructions: All Questions in **Section I** carry equal marks.
Attempt any **THREE** questions in Section I
Question IX in **Section II is COMPULSORY**

SECTION I

Que. 1 Answer in Detail

(i) Define: Thalidomide Tragedy 07

(ii) Why are ADRs Important? What are the important factors in ADR 07

Que. 2 Answer in Detail

(i) Write a note on Principle of WMA Declarations of Helsinki 07

(ii) Write a note: The Belmont Report 07

Que. 3 Answer in Detail

(i) Describe: Role and Responsibilities of Sponsor 07

(ii) Write a note on MedDRA 07

Que. 4 Answer in Detail

(i) Write a note on Essential Document for conduct in clinical Trail. 07

(ii) Describe: Role and Responsibilities of Investigator. 07

Que. 5 Answer in Detail

(i) Describe about different method of designing of study. 07

(ii) Describe: Cross-over design and Replicate design 07

Que. 6 Answer in Detail

(i) Write note on Importance of GCP in clinical research 07

(ii) Write a Note on Factors affecting bioavailability. 07

Que. 7 Answer in Detail

(i) Explain Role of QA-QC 07

(ii) Differentiate between IND and ANDA. 07

Que. 8 Answer in Detail

(i) Explain in brief: IPR (Intellectual property Rights) 07

(ii) Explain Phases of Clinical Trail 07

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SECTION II

Que.9 Answer in short (Any Eight) 08

A. Name the drug regulatory agency of Australia
B. For drug with long half-life,_____ study design is preferred.
C. Give full form of: CRF
D. What is pilot study?
E. CCD means _____.
F. IRB/IEC review _____ documents.
G. Pre-study documents list include _____.
H. Phase-4 is known as _____.
I. What is blinding?
J. When do you consider an event to be serious?