2/28

2903N459

Candidate's Seat No :_____

P. G. D. A. C. R. Examination

Post Graduate Diploma in Advance Clinical Research

March 2019

Time : 2-30 Hours] **[Max. Marks : 100**

Que. 1 (A) Write the following

(i) Journey of a Drug: From Lab to Market **10**

(ii) Roles and Responsibilities of Investigator **10**

OR

(i) History of Clinical Research **10**

(ii) Short Note: Clinical Ethics Committee **10**

Que.1 (B) Answer the following (Any five) **05**

(i) Enlist the stakeholders of a Clinical Trial

(ii) Define: Clinical Hold

(iii) What is the aim of Phase I trials?

(iv) Which application is to be made to regulatory body after preclinical studies?

(v) Define: Phase 0

(vi) Name the current DCGI

(vii) FDA form 1571 stands for _____

Que. 2 (A) Write the following

(i) Abbreviated New Drug Application **10**

(ii) Schedule Y **10**

OR

(i) Design and Analysis of Clinical Trial **10**

(ii) New Drug Application **10**

Que.2 (B) Answer the following (Any five) **05**

(i) Define: Vulnerable Subject

(ii) Enlist at least 3 study designs

(iii) At a clinical trial site, whose responsibility it is to keep the inventory of study drug?

(iv) In India, is it mandatory to register Ethics Committee under CDSCO?

(v) Give full form of SMO

(vi) Name the two parts of ICF

(vii) CRF is to be prepared before the trial initiation. True/False?

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Que. 3 (A) Write the following

(i) Write a note on Standard Operating Procedure **10**

(ii) Format and Content of a Clinical Study Protocol **10**

OR

(i) Essential Documents as per ICH GCP E6 **10**

(ii) QA/QC in Clinical Research **10**

(B) Answer the following (Any five) **05**

(i) Define: Adverse Event

(ii) Enlist five criterion of SAE

(iii) Define: Randomization

(iv) Each individual involved in conducting a trial should be qualified by education, training and experience. True/False?

(v) Give full form of EMEA

(vi) What is the quorum requirement of an EC?

Que. 4 (A) Write the following

a) Overview of BA/BE Studies **10**

b) Principles of ICH GCP E6 **10**

OR

c) Investigator's Brochure **10**

d) Roles and Responsibilities of Sponsor **10**

(B) Answer the following (Any Five) **05**

(i) Can the PI vote during an EC meeting? Yes/No?

(ii) Give full form of LAR

(iii) Define: Source Document

(iv) Give the difference between Crossover Study and Parallel Study

(v) Define: Drop out

(vi) Give full form of IDMC

(vii) EC should retain all relevant records for a period of at least _____ years.

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