2.28

2903N458

Candidate's Seat No :_____

P. G. D. C. T. M. Examination

Post Graduate Diploma in Clinical Trial Management

March 2019

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

Que. 1 (A) Write the following

(i) Phases involved in Clinical Research **10**

(ii) Enlist principles of ICH GCP **10**

OR

(i) Schedule Y **10**

(ii) Intellectual Property Rights **10**

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

(i) Define: Clinical Trial

(ii) Enlist the criterion of SAE

(iii) Give full form of CDSCO

(iv) Name the regulatory agency of Brazil

(v) Give full form of PMS

(vi) Define: CRO

(vii) Give the difference between IND and ANDA

Que. 2 (A) Write the following

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

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

OR

(i) Roles and Responsibilities of Sponsor **10**

(ii) Investigator's Brochure **10**

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

(i) Define: Patent

(ii) Enlist any 5 screening parameters

(iii) Define: Randomization

(iv) Give the difference between open label and blinded study

(v) Give full form of CDA

(vi) Who signs a CTA?

(vii) Give the significance of duty delegation log

P.T.O

N 458-2

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Que. 3 (A) Write the following

(i) Clinical Trial Protocol **10**

(ii) Structure and Elements of ICF **10**

OR

(i) Essential Documents in Clinical Research **10**

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

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

(i) Enlist the three basic principles of an Ethics Committee

(ii) Sulfanilamide disaster happened in the year _____

(iii) Define: Bioequivalence

(iv) Give the difference between single centric trial and multicentric trial

(v) FDA form 1571 stands for _____

(vi) Name the current DCGI

Que. 4 (A) Write the following

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

b) Study Designs of Clinical Trial **10**

OR

c) Standard Operating Procedure **10**

d) Project Management in Clinical Research **10**

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

(i) Define: Placebo

(ii) EC approval is to be obtained by _____

(iii) IB is to be prepared by _____

(iv) Define: Pilot Study

(v) Can the identity of subjects be disclosed to sponsor? Yes/No

(vi) Define: Vulnerable Population

(vii) Define: Pharmacoepidemiology