

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

END SEMESTER EXAMINATION-2015

B.Tech, BTDD and M.Tech Biotechnology

COURSE CODE:11B1WBT837

MAX. MARKS: 45

COURSE NAME: Clinical Trials and Database Management

COURSE CREDITS: 3

MAX. TIME: 3 HRS

Note: All questions are compulsory. Carrying of mobile phone during examinations will be treated as case of unfair means.

Section A

(1X9 =9 marks)

Briefly write about followings.

- A.1 Differentiate between DBMS and RDBMS.
- A.2 Define data definition language with an example.
- A.3 What are secondary biological database? Give an example.
- A.4 Draw DSS configuration for its basic structure?
- A.5 Single ascending dose and multiple ascending doses.
- A.6 Role of Pharmacokinetics in clinical trials.
- A.7 What do understand by term Therapeutic window?
- A.8 Write the important characteristics of Phase III drug testing.
- A.9 Tuskegee experiment?

Section B

- B.1 Explain how artificial intelligence could be incorporated into DSS to make an effective CDSS. Justify your answer with an example. (4.5 marks)
- B.2 Explain any three of the following with reference to CDSS: (1.5 marks each)
(a) Feature, (b) Quick medical reference, (c) EHR and PHR, and (d) What- if analysis.
- B.3 What kind of strategies FDA is embracing to address the challenges in international clinical trials. Discuss. (4.0 marks)
- B.4 Who can be a CRA? Write in detail about the role of CRA in clinical trials. (4.0 marks)

- B.5** How Real-time PCR can be used to evaluate the efficacy of a particular kind of drug in cells. (4.0 marks)

Section C

- C.1** What are the various methodologies for CDSS. Explain information retrieval and heuristic modeling and experimental system with an example of each. (5 marks)
- C.2** Write about the Nuremburg “ Doctor Trails” and Nuremburg code. Ethical conduct in clinical trials can have both good and bad effect. Justify. (5.0 marks)
- C.3** Suppose you want to develop a drug for a particular type of treatment. What kind of steps you will follow to take the drugs to market. (5.0 marks)

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