

JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

TEST – 1 EXAMINATION, SEPTEMBER 2016

B.TECH VII SEMESTER

COURSE CODE: 14B1WBI733

MAX. MARKS: 15

COURSE NAME: Clinical Data Management Systems

MAX. TIME: 1 HR

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

1. How are trial results and study participants' safety being monitored? **2 Marks**
2. Your friend working in a hospital asks your help in identifying patients' attitude and behavior as they utilize services offered by a large hospital system, with questions about contact information for follow-up. Explain as to whether this qualifies as a controlled clinical trial? **2 Marks**
3. What is the purpose of a clinical trial? Explain the four phases. **2 Marks**
4. What are the HIPAA and FISMA rules to secure the clinical data? **2 Marks**
5. For the following design specification, calculate the sample size using poisson approximation. The number of treatment groups are 2 (one control and one test treatment), the outcome measure is death, there is a 5 year follow-up period, the alternate treatment hypothesis is one-sided. However, the allocation ratio (λ) is 0.9, the detectable treatment difference in binary outcome is 0.06, the Type I and II error protection are 0.025, respectively. Losses due to follow-up is 0%, losses due to dropout is 30%, and the treatment lagtime is 0. Use the following table: **3 marks**

Error Level	One-tailed	Two-tailed
0.100	1.282	1.645
0.050	1.645	1.960
0.025	1.960	2.248
0.010	2.326	2.576

6. Define placebo, arms, randomized trials, double blinded trials, and informed consent. **2 Marks**
7. How multi-centre trials are different than single centre trials? **1 Mark**
8. While conducting a clinical trial on asthma (symptoms are coughing at night, tightness in chest, wheezing, etc.) the outcomes measured are:
 - Quality of life questionnaire
 - Symptoms and medication changes from baseline after azithromycin intervention
 - IgG and IgA antibodies at baseline and follow-up
 - Bronchodilator use

While the investigators state that the primary objective or outcome was to investigate the possibility of performing an asthma clinical trial in practice settings, help them to identify the most likely secondary outcomes from this clinical study. **1 Mark**