IIHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-07 (2015-2017), Second Year

Clinical Research and Development

Term Examination

Time: 3.00 Hrs. **M.M. 70**

Note: Attempt five questions, ***question 1 is compulsory****. All questions carry equal marks.*

Q.1 Case Study: (14)

The fifth subject enrolled in a phase 2, open-label, uncontrolled clinical study evaluating the safety and efficacy of a new oral agent administered daily for treatment of severe psoriasis unresponsive to FDA-approved treatments, develops severe hepatic failure complicated by encephalopathy one month after starting the oral agent. The known risk profile of the new oral agent prior to this event included mild elevation of serum liver enzymes in 10% of subjects receiving the agent during previous clinical studies, but there was no other history of subjects developing clinically significant liver disease. The IRB approved protocol and informed consent document for the study identifies mild liver injury as a risk of the research. The investigators identify no other etiology for the liver failure in this subject and attribute it to the study agent.

Describe & analyses the Situation and for further approach to resolve the issue. (14)

Q.2 Describe about Clinical trial site initiation and close-out. (14)

Q.3 Describe Essential Documents in different stages of clinical trial and their uses. (14)

Q.4 Describe following terms: (3.5 each) (14)

a) ICSF b) Block Randomization c) IND

d) Discrepancy Management

Q.5 Describe about Pharmacovigilance and ADR reporting. (14)

Q.6 Describe about essential components of Informed consent form in India. (14)

Q.7 a) Describe the process of new drug development in steps. (7)

b) Describe the purpose of Clinical Research in different phases. (7)