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Register Number :

**7648**

Name of the Candidate :

**P.G. DIPLOMA EXAMINATION DECEMBER 2013.**

**140 — CLINICAL TRIAL, PROJECT FINANCIAL MANAGEMENT AND LIFE SKILLS**

Time : Three hours

Maximum : 100 marks

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**Answer any TWO questions. (2 × 20 = 40)**

1. (a) Write down in detail the steps in clinical trials. Explain the project risk and analysis management.
- (b) List out how a clinical trial in planned executed and documented add a note on the principles of site management.
- (c) What is the importance of clinical trials? Explain the techniques of clinical trials and financial management

**Answer any SIX questions. (6 × 10 = 60)**

2. Write short notes on:
    - (a) What are the key elements of IP accountability?
    - (b) Roles of medical monitor.
    - (c) Briefly write about the clinical trial audit planning with standards.
    - (d) List out the Indian Regulations for clinical research
    - (e) Schedule Y.
    - (f) Explain Audit finding, tracking and trending.
    - (g) What is clinical safety reporting?
    - (h) Comment on Data Sampling.
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