[LF 1014] **OCTOBER 2014** **Sub. Code: 2867**

M.Sc., NON-MEDICAL DEGREE EXAMINATION
SECOND YEAR
(New Regulation)
BRANCH II - BIOSTATISTICS
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code : 282867

Time : Three hours **Maximum : 100 marks**

I. Elaborate on : **(2 x 20 = 40)**

1. How to critically appraise a journal article in randomized control trials?

2. Why do we have to worry about sample size and statistical power in clinical trials - Comments?

II. Write notes on: **(10 x 6 = 60)**

1. CONSORT flow diagram
2. Modified continual assessment method
3. Interim analyses
4. Non – inferiority trials
5. Institutional review board
6. Clinical trials protocol components
7. Standard operating procedures
8. Cluster randomized trials
9. Per protocol analysis
10. Clinical monitoring VS Audit

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[LH 0415] **OCTOBER 2015** **Sub. Code: 2867**

M.Sc., NON – MEDICAL DEGREE COURSES
BRANCH II - BIOSTATISTICS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours **Maximum: 100 marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Define investigational new drug application and describes the component and categories of investigational new drug application.

2. What are the essential documents for the conducting of Clinical trials and its purpose?

II. Write notes on: **(10 x 6 = 60)**

1. Various phases of clinical trial.
2. Informed consent process.
3. Central drug standard control organisation and food and drug administration.
4. Investigators brochure.
5. Randomization.
6. Source documents in clinical trial.
7. Vulnerable subjects.
8. Roles and responsibilities of regulatory authority in relation to clinical trial.
9. What are the responsibilities of clinical data manager?
10. Define the followings:
    (i) Blinding (ii) Comparator (iii) Good clinical practice

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[LJ 1016] OCTOBER 2016 **Sub. Code: 2867**

M.Sc. BIOSTATISTICS EXAMS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours **Maximum: 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Why the Randomization process is needed for clinical trial by explain its methods?

2. What is meant by factorial design? Discuss its characteristics and also list a few trials using factorial design.

II. Write notes on: **(10 x 6 = 60)**

1. Clinical bias and statistical bias.
2. Stopping rules for trials.
3. Consort flow diagram.
4. Non- inferiority trial.
5. Meta analysis.
6. Continuous sequential statistical techniques.
7. Controlling the risk of false positive clinical trial.
8. Protocol and manual of operation for clinical trials.
9. Types of trials.
10. Vulnerable subjects.

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[LL 1017] OCTOBER 2017 **Sub. Code: 2867**

M.Sc. BIOSTATISTICS EXAMS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code : 282867

Time : Three hours **Maximum : 100 marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Define randomised control trial and its applications.

2. What are the crossover trials and its advantages and disadvantages?

II. Write notes on: **(10 x 6 = 60)**

1. Essential documents for conducting clinical trial.
2. Responsibilities of clinical data manager.
3. Clinical trial bias.
4. Purposes and applications of meta analysis.
5. Needs of randomization.
6. Preclinical studies.
7. Stopping rules for trials.
8. Characteristics of factorial design.
9. Clinical trial study.
10. Ethical issues for publication of data analysis.

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[LP 1019] OCTOBER 2019 **Sub. Code: 2867**

M.Sc. BIOSTATISTICS EXAMS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code : 282867

Time : Three hours **Maximum : 100 marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Elaborate on the detailed manner of clinical trial registration and discuss in the brief manner of Challenges in Administering a Clinical Trials Registry.

2. Describe the various statistical methods in the randomized clinical trials and elaborate the factorial design and its characteristics with examples.

II. Write notes on: **(10 x 6 = 60)**

1. Method of generating randomization sequence.
2. Method of allocation concealment.
3. Blinding and masking.
4. Intellectual property rights.
5. Impact of ethics on research.
6. DCGI approval.
7. Statistical bias.
8. Preclinical research.
9. Meta analysis.
10. Clinical trial.

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