[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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[LN 1018] OCTOBER 2018 **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. Explain the role of various methods of randomization for clinical trials.

2. Discuss in detail data safety monitoring board in clinical trials.

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

1. Characteristics of factorial design.
2. Advantages of crossover trials.
3. Purpose of Meta analysis.
4. Consort flow diagram.
5. Non- inferiority trial.
6. Group sequential trials.
7. Types of trials.
8. Bias in clinical trials.
9. Interim analysis
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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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 0321] **MARCH 2021** **Sub. Code: 2867**

(OCTOBER 2020 EXAM SESSION)

M.Sc. BIOSTATISTICS

SECOND YEAR (From 2011-2012 onwards)

PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code : 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

I. Elaborateon: **(2 x 20 =40)**

1. Explain the factorial design and its applications in clinical trials.

2. What are the different Phases of clinical Trails and elaborate randomization and stratification in clinical trials.

II. Writenoteson: **(10 x 6 =60)**

1. Crossover trials.
2. Block randomization.
3. What are the risks of participating in a clinical research study?
4. Trial data and data management principles.
5. Clinical Bias and Random Error
6. Roles and Responsibilities of a Clinical Research Coordinator
7. Method of allocation
8. Method of generating randomization sequence.
9. Equivalence trials
10. Ethics of Clinical Trials

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 0122] **JANUARY 2022** **Sub. Code: 2867**
(OCTOBER 2021 EXAM SESSION)

M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012 onwards)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT
Q.P. Code : 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

I. Elaborateon: **(2 x 20 =40)**

1. Write in detail about Sequential and Group Sequential Designs in Clinical Trials.

2. Explain in detail about randomized control trial and its applications.

II. Writenoteson: **(10 x 6 =60)**

1. Blinding in clinical trials
2. Preclinical Research
3. Who can participate in a clinical research study?
4. Difference between an observational clinical research study and a clinical trial.
5. Informed consent.
6. Interim analysis
7. Crossover trials
8. Multiple testing in clinical trials
9. Trial data and data management principles.
10. Essential Documents in Clinical Trials.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 1022] **OCTOBER 2022** **Sub. Code: 2867**

M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012 onwards)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code : 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

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

1. Describe the importance of Randomization and different methods of Randomization in Clinical Trials.

2. Elaborately discuss the concepts of clinical trial and data management principles in clinical trials.

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

1. Preclinical research.
2. Block Randomization techniques.
3. Blinding and masking.
4. Impact of ethics in research.
5. Importance of Informed consent.
6. Interim analysis.
7. Crossover trials.
8. Sequential trials.
9. How to avoid selection bias?
10. DCGI approval.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 1023] **OCTOBER 2023** **Sub. Code: 2867**

M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012 onwards)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

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

1. Discuss the importance of Clinical trials and their phases. Also, describe about the clinical trial registry in India.

2. Describe the importance of Data safety monitoring board concepts and its management.

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

1. Clinical trials protocol components.
2. Non – inferiority trials.
3. Standard operating procedures.
4. Per protocol analysis.
5. Stopping rules for trials.
6. Consort flow diagram.
7. Meta-analysis.
8. Characteristics of factorial design.
9. Ethical issues for publication of data analysis.
10. Types of bias in the clinical trial.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 1024] **OCTOBER 2024** **Sub. Code: 2867**

M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012 onwards)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

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

1. What are the essential documents for conducting Clinical trials and their purpose?

2. Elaborately discuss the concepts of clinical trial and data management principles in clinical trials.

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

1. CONSORT flow diagram.
2. Vulnerable subjects.
3. Clinical bias and statistical bias.
4. Responsibilities of the clinical data manager.
5. Purposes and applications of meta-analysis.
6. Stopping rules for trials.
7. Ethical issues for publication of data analysis.
8. Superiority vs Equivalence trial.
9. Sequential trials.
10. Needs of randomization.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[AHS 1025] **OCTOBER 2025** **Sub. Code: 2867**

M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours **Answer ALL Questions** **Maximum: 100 Marks**

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

1. Write in detail about Sequential and Group Sequential Designs in Clinical Trials.

2. Explain the Phases of Clinical Trials in detail with appropriate examples.

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

1. Explain the following:
   a) What is a clinical trial?
   b) What are the benefits and risks of being in a clinical trial?
   c) What is an Informed Consent?
   d) What is an Institutional Review Board?
2. Explain Good Clinical Practice and write down the principles of GCP.
3. What is a per-protocol analysis?
4. Explain the roles and responsibilities of the Regulatory Authority in clinical trials.
5. Write in detail about Multiple testing.
6. What are Blinding and Masking? Briefly explain the need for Blinding and Masking in clinical trials.
7. Write in detail about the Standard operating procedures for Clinical Data Management.
8. What are cluster-randomized trials?
9. Explain the stopping rules in clinical trials.
10. Briefly explain Intention to Treat analysis.

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