[KX 825] **SEPTEMBER 2010** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(Regulations 2008-2009)

(Candidates admitted from 2008-2009 onwards)

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer ALL questions

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

1. Define Clinical Trials?
   Discuss in detail five various phases involved in drug development process.

2. Discuss the composition, responsibilities and procedures of IRB/IEC.

II. Write notes on: **(6 x 5 = 30)**

1. Significance of post marketing surveillance.
2. Roles and responsibilities of Investigations.
3. Study designs in a clinical trail.
4. Informed consent process.
5. ICH guidelines in clinical trials.
6. Purposes of an audit in a clinical trial.

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[KZ 825] **OCTOBER 2011** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 100 marks**

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. a) Define investigational new drug application and describes the component and categories of investigational new drug application.	17	40 min.	20
b) What are the essential documents for the conducting of clinical trials and its purpose?			
2. a) Roles and responsibilities of auditors in clinical research			
b) Define serious adverse event in clinical trial and responsibilities of investigators in reporting	17	40 min.	20

II. Write notes on :

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

[LB 825] **OCTOBER 2012** **Sub. Code: 3825**

PHARM. D / POST BACCALAUREATE DEGREE EXAMS

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : 3 hours **Maximum : 100 marks**

(180 Min)

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. (A) Explain in details about the institutional review board / independent ethics committee compositions and its functions in clinical research. (B)Define clinical trial and various phases.	17	40	20
2. (A) what are the ethical guidelines in clinical research? (B) Define data management and its component in clinical trials.	17	40	20

II. Write Notes on :

1. Protocol and its components.	4	10	6
2. 2.Roles and responsibilities of sponsor in clinical trials.	4	10	6
3. Define investigational new drug application and its procedure for submission.	4	10	6
4. Clinical research co ordinator.	4	10	6
5. Post marketing surveillance and its methods.	4	10	6
6. 6.Role of auditors in clinical trial.	4	10	6
7. What are the roles and responsibilities of sponsor in reporting of serious adverse events?	4	10	6
8. Electronic data capturing system and its role in clinical trial.	4	10	6
9. Protocol amendment in clinical research.	4	10	6
10. Data migration and archiving.	4	10	6

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[KD 825] **OCTOBER 2013** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

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

1. What is ANDA?
   What are the drugs come under ANDA?
   What is meant by generic drugs?
   Write a note on post marketing surveillance.

2. What is Institutional human ethical committee?
   Give the composition, qualification required for the members.
   Explain the functions of the committee.

II. Write notes on: **(10 x 3 = 30)**

1. Explain the importance of Pharmacological information in drug discovery.
2. Name various chemical characteristics of the drug.
3. Write a not on GCP.
4. What are the challenges faced by the investigator in clinical trials.
5. Write a not on schedule Y.
6. Explain the responsibility of the auditors in clinical trials.
7. Explain the protocol involved in data management in clinical research.
8. Differentiate Phase II & Phase III clinical trials.
9. Why randomization is important in clinical research?
10. Write the significance of preclinical testing in clinical research.

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[LE 825] **APRIL 2014** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

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

1. a) What is clinical research and why do we need to conduct research?
   b) What are the different stages of drug development process?
2. a) Roles and responsibilities of contract research organizations in clinical research.
   b) Define Investigator's brochure and describes about its components.

II. Write notes on: **(10 x 3 = 30)**

1. Good clinical practice and its principles.
2. Informed consent process.
3. Central drug standard control organisation and food and drug administration.
4. Various ethical guidelines in clinical research.
5. Safety monitoring in clinical trials.
6. Source documents in clinical trial.
7. Vulnerable subjects.
8. Roles and responsibilities of Investigator in clinical trial.
9. What are the responsibilities of regulatory authority in clinical research?
10. Define the followings:
    a) Case report form (CRF).
    b) Impartial witness.
    c) Schedule-Y.

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[LF 825] **OCTOBER 2014** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(2009-2010 Regulation)

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(4 x 10 = 40)**

1. Define investigational new drug application and describes the component and categories of investigational new drug application.
2. Discuss in detail the overview of regulatory environment in Europe.
3. Explain in detail the roles and responsibilities of regulatory authority and contract research coordinators.
4. Describe in detail the various approaches to drug discovery.

II. Write notes on: **(6 x 5 = 30)**

1. Write short note on various phases of clinical trials.
2. Describe briefly the ethical guidelines in clinical research.
3. Write a note on data management and its components.
4. Explain briefly the ICH guidelines.
5. Write note on informed consent process.
6. Post marketing surveillance.

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[LG 825] **APRIL 2015** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(2009-2010 Regulation)

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(4 x 10 = 40)**

1. Briefly write on:
   a) Double blind clinical trials.
   b) Open label clinical trials.
   c) Retrospective studies.
2. What is mean by informed consent?
   Explain content and method of administration of informed consent as per regulatory authorities in clinical trials.
3. What are dosage forms? Give example. Explain different type of dosage forms.
4. Explain the protocols and method of reporting ADR under Pharmacovigilance.

II. Write notes on: **(6 x 5 = 30)**

1. How SOPs are prepared to meet the GLP standards?
2. Write the ethical consideration in the conduct of clinical trials.
3. Write a note on safety monitoring in clinical trials.
4. What are the major challenges observed in implementation of the regulatory guidelines in clinical trials?
5. Briefly write the data management in clinical trials.
6. Explain:
   a) Placebo.
   b) Human Subjects.
   c) Candidate drug.

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[LH 825] **OCTOBER 2015** **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE) DEGREE EXAMINATION

(2009-2010 Regulation)

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time: Three Hours **Maximum: 70 marks**

Answer ALL questions

I. Elaborate on : **(4 x 10 = 40)**

1. Define Clinical Trials. Discuss in detail five various phases involved in drug development process.
2. What are the essential documents for the conducting of clinical trials and its purpose?
3. What is Institutional human ethical committee? Give the composition, qualification required for the members and explain the functions of the committee.
4. Discuss the roles and responsibilities of auditors in clinical research.

II. Write notes on : **(6 x 5 = 30)**

1. Write in detail the central drug standard control organization guidelines.
2. Explain briefly the informed consent process.
3. Write a note on data management.
4. Describe briefly the ethical guidelines in clinical research.
5. Write briefly the Source documents in clinical trial.
6. What are the responsibilities of clinical data manager?

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[LI 825] APRIL 2016 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Explain the Pharmacological and Toxicological approaches to Drug discovery.
2. Describe the roles and responsibilities of Investigators and Clinical Research associates.
3. Discuss the challenges in the implementation of Good Clinical Practice guidelines.
4. Describe the guidelines of Central drug standard control organization.

II. Write notes on: **(6 x 5 = 30)**

1. Abbreviated New Drug Application.
2. Various types of post marketing surveillance.
3. Ethical principles in Clinical research.
4. Explain the contents in Investigational new drug application.
5. Safety monitoring in Clinical research.
6. Responsibilities of Institutional review board.

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[LJ 825] OCTOBER 2016 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Discuss in detail the overview of regulatory environment in Europe and USA.
2. What is informed consent? Explain content of informed consent as per regulatory authorities in clinical trials.
3. What are the different methods of post marketing surveillance?
4. Discuss the importance of safety monitoring in clinical trials.

II. Write notes on: **(6 x 5 = 30)**

1. Briefly write on Case Report Form.
2. Role and responsibility of clinical research co-ordinator.
3. Write note on Impartial witness.
4. Purpose of an audit in clinical trial.
5. Investigational new drug application.
6. Why randomization is important in clinical research?

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[LK 825] MAY 2017 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. What are the essential documents for the conducting of clinical trials and discuss the purpose of the same?
2. Explain the functions of IRB in clinical research.
3. Define Investigator's brochure and describe about its components.
4. Elaborate on the roles and responsibilities of regulatory authority in relation to clinical trial.

II. Write notes on: **(6 x 5 = 30)**

1. Write a note on GCP.
2. Explain the importance of pharmacological information in drug discovery.
3. Preclinical testing in clinical research.
4. Informed Consent Process.
5. Safety monitoring in clinical trials.
6. Explain briefly the ICH guidelines.

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[LL 825] OCTOBER 2017 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Define Clinical trials. Discuss in detail about the various phases involved in Clinical trial and detail.

2. Discuss in detail about various approaches of Drug discovery.

3. Role and responsibilities of principal investigator in clinical trials.

4. Define Investigational New Drug Application (INDA) and discuss the components and categories of INDA in detail.

II. Write notes on: **(6 x 5 = 30)**

1. Post marketing surveillance.
2. Write note on Schedule – Y.
3. Safety monitoring in clinical trials.
4. Discuss in brief about different dosage forms.
5. Preparation of Informed Consent Form (ICF).
6. Role and responsibilities of data management team in clinical trials.

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

[LM 825] MAY 2018 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Define Bias. Discuss in detail about various sources of bias and methods to avoid Bias.

2. Describe in detail about regulatory setup that governs the clinical research process in India.

3. Explain the components of clinical research protocol and the process of protocol preparation.

4. Discuss in detail about various methods used in post marketing safety monitoring process.

II. Write notes on: **(6 x 5 = 30)**

1. Write a note on general parameters involved in inclusion and exclusion criteria.
2. Write the responsibilities of sponsor's in clinical trial.
3. Write the functions of data and safety monitoring board.
4. Define IND application and write contents of IND application.
5. Write a short note on drug discovery process.
6. Write the safety issues on the investigational new drugs.

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

[LN 825] OCTOBER 2018 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Describe the types of control and significance of using control in clinical trials.

2. Write the essential elements of informed consent form and problems in informed consent.

3. Discuss in detail about role and responsibilities of principal investigator in clinical research.

4. Explain components of ICH-GCP guidelines and write its significance.

II. Write notes on: **(6 x 5 = 30)**

1. Define randomization. Write a note on static and adaptive designs.
2. Write about functions of various regulatory divisions of US-FDA.
3. Write a short note on investigators brochure.
4. List the type of audits and its importance in clinical trials.
5. Write a note on new drug application submission.
6. Define parallel and cross over study designs of clinical research.

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

[LO 825] MAY 2019 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Describe the importance and requirements of various phases of clinical trials.
2. Discuss in detail about the role and responsibilities of clinical research associate.
3. Describe the clinical trial data management process and its benefits.
4. Explain in detail about essential documents of clinical research process.

II. Write notes on: **(6 x 5 = 30)**

1. Write a note on blinding and un-blinding.
2. Give a note on constitution and responsibilities of institutional review board.
3. Write a brief note on case record form.
4. Write a short note on regulatory setup in Europe.
5. Briefly write about study site audits and its significance.
6. Write a short note on informed consent process.

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

[LP 825] OCTOBER 2019 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Write about the ICH guidelines in clinical trials.
2. Describe the various pharmacological and toxicological approaches to drug discovery.
3. Give an account on Abbreviated New drug Application.
4. Discuss the roles and responsibilities of sponsors and investigators in clinical research.

II. Write notes on: **(6 x 5 = 30)**

1. Regulatory environment in India.
2. Vulnerable subjects.
3. Challenges in implementation of guidelines in clinical trials.
4. Responsibilities of clinical research coordinator in clinical research.
5. Case Report form in study design.
6. Significance of Post marketing surveillance.

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