Bioinformatics Institute of India

H-109, Ground Floor, Sector-63, Noida-201307, UP. INDIA
Tel.: 0120-4320801 / 02, M. 09818473366, 09810535368
Email: info@bii.in, Website: www.bii.in

INDUSTRY PROGRAM IN
CLINICAL TRIALS DATA MANAGEMENT & PHARMACOVIGILANCE

Examination Assignments

April, 2017

Instructions for Examination Assignments – April, 2017

- Electronic (email), printed and hand written submission of the assignments are acceptable.
- Do not copy from the answers of other participants. If it is noticed the assignment of such participants will not be accepted.
- The assignment for each paper should be written separately. Do not write the assignment for all the papers in continuity. However, all the assignments are to be submitted together.
- No two or more participants should submit their assignments in same envelope.
- The participants should mention their Name and Enrollment Number on each page of submitted assignment copy.
- The last date of submission of Assignments is **30th April, 2017.**
- The assignments have to be submitted to:

  The Program Director

  Bioinformatics Institute of India

  H-109, Ground Floor, Sector-63, (Behind Haldiram) Noida-201307

  U.P. INDIA
- Participants are advised to keep a photocopy of submitted assignments.
- The participants should mention their Name and Enrollment Number on the envelope.
- The participant should also mention “Examination Assignment” at the top of the envelope.
- The result will be announced by 2nd week of June, 2017.
- For any query mail us on info@bii.in

Module 1: Pharmacovigilance, Risk Management, & Compliance to Clinical Safety

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short Answer Type Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. Give the structure of crisis management.
2. Define International Birth Date.
3. Define electronic record.
4. What are the function and goals of Drug Safety Oversight Boards?
5. Write a short note on Orphan Drug Act 1983?
6. Discuss the role of the Center for Drug Evaluation and Research?
7. Draw GMP4 V-Model for validation of automated system.

SECTION - B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What is FDA policy on DTC advertising?
2. Give the complete structure and function of Agency Crisis Team.
3. Discuss establishment, members and goals of the Drug Safety Oversight Board (DSB).
4. Explain black box Warning promotion.
5. Explain FDA 21 CFR PART 11?
6. Explain the life cycle of product?
7. What is the requirement of pharmacovigilance management in pharmaceutical industries?

Module 2: Pharmacovigilance Regulation to Clinical Safety

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short Answer Type Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. Difference between CCDS and CCSI?
2. What do you understand by PSUR?
3. What is Direct Healthcare Professional Communication?
4. What is QPPV? Explain.
5. What are the role and responsibilities of the marketing authorization holder for Pharmacovigilance?
6. Explain DHPC?
7. What was the purpose of Rapid Alert in Pharmacovigilance?

SECTION B

Long answer type question: (250-300 Words) **5 × 10 = 50 Marks**

1. What are the requirements for the periodic update reports?
2. What are the key principles for Public Communication on Medicinal Products?
3. What are the functions and procedure of centralized marketing authorization?
4. Explain the different phases of DHPC in detail.
5. What is the difference between RMS and CMS states in Pharmacovigilance?
6. What are the requirements for Pharmacovigilance systems, monitoring of compliance and Pharmacovigilance inspections? Explain in detail.
7. How to prepare individual case safety reports parent-child/foetus cases?

Module 3: Adverse Drug Reactions Reporting & Signal Detection Systems

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short Answer Type Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is yellow card scheme?
2. What are indirect adverse effects?
3. What do you mean by organ selective injury?
4. Differentiate between Overdosing and Poisoning with suitable examples.
5. How neural networks are used in finding adverse reactions?
6. What do you mean by therapeutic ineffectiveness?
7. Write short note on side effect.

SECTION B

Long answer type question: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain The French Imputability Method and its basic principles?
2. Explain “Polymorphism related to cancer chemotherapy”.
3. Describe the adverse drug reaction reporting in the United States.
4. What is the methodology of spontaneous reporting?
5. Write the name of two national agencies with their functions that are responsible for licensing and pharmacovigilance activities for human medicinal products?
6. Write the frequency and variety of medication use among pregnant women?
7. What according to you are the future challenges for Pharmacovigilance with respect to monitoring for pregnancy exposure and pregnancy prevention for known human teratogens?

Module 4: Bio-statistical Analysis of Clinical Trials Data

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short Answer Type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What do you mean by open ended question?
2. What do you mean by flat doses?
3. What is screening trial?
4. Write short note on CRF.
5. What are the type I and type II error in hypothesis testing?
6. What are the ethical challenges related to micro dosing?
7. Write the role of sampling in clinical trial.

SECTION B

Long Answer type Questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Briefly explain the Hypothesis Testing?
2. Explain in detail the responsibility of the investigator.
3. Discuss the reasons for patient dropouts from the trials.
4. What do you think is the significance of clinical trial and what are the future challenges that are to be faced?
5. Briefly explain the phases of clinical trial.
6. What is meant by Sampling ? Explain different types of sampling methods.
7. Micro-dosing or Phase-O is a recent phase introduced in clinical trials. Explain its importance & procedure.

Module 5: Clinical Trials & Regulation Analysis

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is CRF? Write down its application also.
2. Difference between Pharmacokinetics and Pharmacodynamics.
3. What is phase 0 dosing?
4. What is dose Nuremberg code?
5. What are the key components of trial protocol?
6. Explain the following terms:
   (i) SOP (ii) IDMC
   (iii) Nocebo Effect (iv) Oncogenicity
   (v) ICH
7. Explain psychological and placebo effect.

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain the guidelines of general prospective protocol.
2. What is the need of clinical trials?
3. What are the advantages and disadvantages of micro dosing?
4. Why is necessary to enhance electronic clinical trials?
5. Explain the randomization procedures in clinical trials.
6. Explain TER and STER in detail.(with diagram)
7. Explain in detail the drug development process and the phases of clinical research.

Module 6: Clinical Trials Data Management

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is remote data entry?
2. Write short note on data modeling.
3. Differentiate between raw data and processed data.
4. What can be the reasons for errors in coding?
5. What are the two steps of SAS Program?
6. Explain online data management.
7. Write a note on electronic data capture?

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain tracking of CRF pages.
2. What do you understand by the term coding of data?
3. Give an overview of the output delivery system?
4. Briefly explain step by step approach to Clinical trials data management.
5. What according to you is the role of computers in clinical trials? Explain.
6. Computers have simplified the work of clinical trials? Present your opinion.
7. Write some advantages & disadvantages of online trials?

Module 7: ICH – GCP Guidelines for Clinical Trials

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What do you mean by blinding or masking?
2. What is a trial design?
3. What do you mean by nonclinical pharmacology?
4. What are multicentre trials?
5. What are the necessities for medical care of a trial subject?
6. Write a note on an independent ethics committee?
7. What are the duties of a sponsor in the case of premature termination?

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What should be the content of investigator's brochure?
2. How ICH and GCP guidelines have led to safer methods of clinical trials?
3. What is the criterion of compensation to subjects & investigators?
4. Discuss the principles of ICH GCP?
5. Explain Pharmacokinetics in detail.
6. Illustrate: "Independent ethics committee"?
7. What do you mean by premature termination of a trial? What could be the reason for it?

Module 8: Contract Research

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is the role of FWA?
2. Write short note on Diabetic Neuropathy.
3. Write short note on Eli Lilly.
4. What do you understand by bio-availability of a drug?
5. Write a short note on infringement of contract.
6. Write short note on angioplasty?
7. Mention 5 criteria that a sponsor looks for in a CRO

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain the ethical issues involved in Contract Research.
2. What are the positive & the negative aspects of academic research?
3. What do you understand by New Drug Application?
4. Explain Formulation, Reformulation and Deformulation.
5. Contract research is believed to be an emerging opportunity. Put forth your views.
6. Write a detailed note on Jawaharlal Nehru University as academic research organization.
7. India is considered as a home for outsourced research. What are the advantages associated with the country to work in the pharmaceutical sector?

Module 9: Assurance & Control of Pharmaceutics

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is ATR?
2. Write short note on Optical rotation methods.
3. Write a short on the batch certificate of pharmaceutical product.
4. Write short note on the *p-plan.*
5. Write a note on product license?
6. Define term shelf-life?
7. What is phase solubility analysis?

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What do you mean by Analytical validation of pharmaceutical product? Explain.
2. Explain accuracy, precision and reproducibility with examples.
3. Give an account of the different methods used in determining the purity of reference substances.
4. Describe the assessment of safety and efficacy.
5. What according to you is the role of international trade in broadening the pharmaceutical market of a country?
6. Write a detailed account on infrastructure of First-stage laboratory for drug surveillance?
7. Explain bioequivalence studies in humans with an example.

Module 10: Medical Writing and Documentation

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What do you mean by an abstract?
2. What is the purpose of medical writing?
3. Write short note on scientific review of an article.
4. Write short note on Peer-Review system.
5. Write short note on journals.
6. What are the essential documents for a clinical trial?
7. Differentiate between ‘in-house’ and ‘outsourced’ medical writing

SECTION B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What are common problems faced while writing an abstract?
2. What is the importance of medical writing for healthcare industry?
3. Explain regulatory writing and educational medical writing.
4. Why is a Scientific Administrative Review (SAR) process required?
5. What is the importance of clinical documentation in clinical trial?
6. Medical writing promises to be the next booming field with respect to job. Do you agree with the statement?
7. What should be considered in an ethical review?