Bioinformatics Institute of India

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PROFICIENCY PROGRAM IN 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: 100

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 targeted clinical investigation?
2. What is CSV?
3. What were FDA actions under CPG policy?
4. Differentiate between cosmetics Vs drugs.
5. Define the term “frequency of adverse drug reactions”?
6. Write short note on PDUFA.
7. What are case control studies?

SECTION B

Long Answer type questions: (250-300 Words) **5× 15 = 75 Marks**

1. What type of warning contained in Black Box? Explain.
2. Explain the switch process to go directly OTC.
3. Does Government Regulation have impact on Prescription Drug Marketing & Promotion? Explain
4. Explain the Drug utilization study.
5. What are the issues concerning drug safety?
6. Explain the following:
   a) CDER (Center for Drug Evaluation & Research)
   b) PDMA (Prescription Drug Marketing Act).
7. Explain the benefits of 21 CFR Part11 to Organization?

Module 2: Adverse Drug Reactions and Safety Reports
Examination Assignment April, 2017

Max. Marks: 100

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 side effect?
2. What do you mean by data integrity analysis?
3. What do you mean by prenatal drug exposure?
4. What do you mean by exposure?
5. What do you mean by ERMS action plan?
6. Define linkage analysis?
7. Explain in brief the Yellow Card Scheme.

SECTION-B

Long Answer type questions: (250-300 Words) **5 × 15 = 75 Marks**

1. Describe 'Pharmacovigilance and drug safety'?
2. Explain the type B adverse effect.
3. Explain the steps in designing the structure of our database and creating Analytical data files.
4. Discuss the International Conference on Harmonisation.
5. What do you think are the benefits and risk of any therapy? Explain giving examples.
6. Explain spontaneous reporting with an example.
7. Define Signal Detection. Give a brief account on Signal Detection & Pharmacovigilance.

Module 3: Clinical Trials & Regulations
Examination Assignment April, 2017

Max. Marks: 100

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 a treatment?
2. What is Case Report Form?
3. What are inclusion criteria and exclusion criteria?
4. What are the characteristics of patient reported outcome?
5. State the reasons for patient dropouts.
6. Write a note on CRO's?
7. Discuss Phase IV trials (post-licensing studies).

SECTION-B

Long Answer type questions: (250-300 Words) **5 × 15 = 75 Marks**

1. Explain the declaration of Helsinki 1964.
2. Define a dose. Give the overview of dose selection.
3. What are inclusion criteria and exclusion criteria?
4. Explain patient dropouts. What are the reasons for the patient drop out?
5. Give the advantage of India with regards to clinical trials.
6. Mention the rules & principles for testing the effectiveness of new drugs?
7. Define term Protocol. State & explain each component of Clinical Trial protocol.

Module 4: Signal Analysis & Pharmacovigilance Regulations
Examination Assignment April, 2017

Max. Marks: 100

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 signal testing?
2. What do you mean by detection of group-effect?
3. What are the competent authorities?
4. Write a short note on Crisis Management Plan.
5. What do you mean by signal selection and follow-up in Pharmacovigilance?
6. What are the limitations of the human safety database?
7. What are interventional studies?

SECTION-B

Long Answer type questions: (250-300 Words) **5 × 15 = 75 Marks**

1. Discuss use and implementation of a Bayesian confidence propagation neural network (BCPNN).
2. Explain model for a Periodic Safety Update Report (PSUR).
3. Explain the methodology of spontaneous reporting in signal detection.
4. Do you think the concept of signal detection has opened the way for further futuristic research and why?
5. Explain the use of a Bayesian Method for signal detection and analysis.
6. “Pharmacovigilance is an essential element for assessing safety of medicines.” Justify the statement.
7. Give short note on the following:
   a) Drug Dependence
   b) Drug Overdose
   c) Idiosyncrasy

Module 5: Pharmacovigilance Management & Importance

Examination Assignment April, 2017

Max. Marks: 100

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 are multiple ascending doses?
2. Write a short note on DESI.
3. What is CDER?
4. What are herbal and traditional medicines?
5. What is orphan drug act 1983?
6. What are good manufacturing practices?
7. What are the opportunities in the field of pharmacovigilance?

SECTION-B

Long Answer type questions: (250-300 Words) **5 × 15 = 75 Marks**

1. Explain the WHO program for International Drug Monitoring.
2. Explain the Non-Traditional Promotion-FDA policies.
3. What are the improvements needed in post marketing surveillance?
4. Illustrate the five FDA centers that regulate specific marketing and promotional areas of health related products.
5. Explain GAMP V-Model for validation of automated systems.
6. Explain the following briefly:
   a) Cosmetics Vs Drugs
   b) Prescription Vs OTC Drugs
7. With the help of a flow diagram explain how FDA regulates marketing and promotion of drugs.