Bioinformatics Institute of India

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Industry Program in Clinical Trials Research and Administration

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: 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. Explain Formulations, Reformations and Deformulations.
2. What is drug delivery?
3. What are the dominating areas of CRO operations?
4. Write a note on vaccine research.
5. What do you understand by direct & indirect costs involved in contract research?
6. What is the role of biostatistics in clinical research?
7. Give a brief note on historical perspective & evolution of contract research system.

SECTION - B

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

1. Give the view for trends of contract research.
2. What are the benefits of using information technology in Pharma Research?
3. What are the guidelines for the preparation of a contract research organization master file (CROMF)?
4. Name few pharmaceutical firms from directory of Pharma companies & organizations.
5. What are the trends affecting the CRO industry?
6. What is contract research organization master file (CROMF)?
7. What are the advantages to pharmaceutical & biotechnological companies by outsourcing of drug discovery & development?

Module 2: Contract Research and Clinical Trial Environment

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. Explain comparative efficacy and safety.
2. What are the risks associated with participating in a clinical trial?
3. Give an introduction on Complementary & Alternative Medicine (CAM).
4. What do you understand by assay sensitivity?
5. What is the role of Institutional Review Board in clinical trials?
6. Explain in brief placebo concurrent control.
7. What are the seven basic components of clinical trials budget?

SECTION - B

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

1. What should be the characteristics that a candidate should have before entering the drug discovery contract research?
2. What are the advantages and disadvantages of placebo-controlled trials?
3. Discuss the importance of clinical trials.
4. Discuss your opinion on contract research & clinical trials environment in India and also, is there any need of initiatives to be taken by government in this sector?
5. What are the ethical concerns associated with placebo-controlled trials?
6. What are the important points that must be considered by the person, who is thinking of joining a clinical trial?
7. Describe the links where the information of drugs is available.

Module 3: ICH -GCP Guidelines - International Conference of Harmonization

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 are Source Documents?
2. Define the term inspection.
3. What is Interim clinical trial report?
4. What do you meant by audit?
5. What is adverse drug reaction?
6. What do you understand by impartial witness of a clinical trial?
7. Define the term subject identification code.

SECTION - B

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

1. What are the duties of an investigator in providing medical care to the trial?
2. Write the contents of a clinical trial protocol and protocol amendments.
3. What are the responsibilities of a sponsor regarding quality assurance & quality control?
4. Write a note on Institutional Review Board?
5. How ICH guidelines for good clinical practices have proved to be a strong way for safety of human subjects in clinical trials?
6. Write the composition, functions and operations of IRB/IEC.
7. What are the actions to be taken by investigator in case of premature termination or suspension of a trial?

Module 4: ICMR -Guidelines on Biomedical Research on Human Subjects

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 somatic cell gene therapy?
2. Explain prenatal testing?
3. What is Helsinki Declaration?
4. Write a detailed note on human Genome Project.
5. What do you meant by cross-sectional studies?
6. What do you meant by critical and non critical devices with example?
7. What are the conditions to be considered when taking children for clinical trials?

SECTION - B

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

1. What care should be taken of compensation for participation?
2. Transplantation from animals to men has benefits but equally harmful. Present your opinion.
3. What is the protocol for submission of application for a researcher?
4. What are the guidelines for live donor transplants?
5. Explain “Maintaining confidentiality of epidemiological data”?
6. What should be included in the protocol for submission of application by a researcher?
7. What are the benefits of using information technology in Pharma Research?

Module 5: 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 is trial monitoring?
2. What do you mean by micro dosing?
3. What are randomized trials?
4. What is Case record form and trial documentation?
5. Give a brief note on era of modern clinical trials.
6. Write a short note on single ascending dose.
7. What are the guidelines for internal audit?

SECTION - B

Long answer type questions: (250-300 Words) **2 × 10 = 20 Marks**

1. Explain the two phases involved in validation of analytical method.
2. Why India is emerging as first choice for conducting clinical trials?
3. What is the role of information technology in clinical trials?
4. Why pregnant patients are excluded from clinical trials?
5. Draw a flow diagram of approval /authorization procedures in pharmaceutics?
6. How did James Lind invent prevention for scurvy?
7. Give a brief note on the European Bioethics Convention?

Module 6: Biostatistics
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 are random variables?
2. What is the main difference between histogram & polygon?
3. What do you mean by kurtosis?
4. Give the formula for conditional probability.
5. What are the advantages and disadvantages of mode?
6. What is a confidence interval?
7. Explain standard deviation?

SECTION - B

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

1. Explain random and non random sampling.
2. What is sampling distribution? Write its properties and advantages.
3. Discuss the role of biostatistics in Bioinformatics.
4. Explain multiplication theorem of probability.
5. What is vital statistics? Give utility.
6. What do you understand by measure of central tendency? Explain with an example.
7. What is Probability? Write its properties, characteristics, advantages and disadvantages.

Module 7: Schedule Y
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. Write a note on bioavailability.
2. What are advantages of Dose-response trials?
3. What is post marketing surveillance?
4. What do you understand by essential safety pharmacology?
5. Write a note on local toxicity studies.
6. What do you meant by Genotoxicity?
7. What are the objectives of the human pharmacology (phase I) studies?

SECTION - B

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

1. Explain the third group of FDCs.
2. Explain the responsibility of the ethics committee.
3. Explain any one standard allergenicity/hypersensitivity test.
4. Ignorance of rules to be followed during clinical trials in special as well as general populations leads to hazardous results for society. Give your opinion.
5. How male fertility studies are carried out using a rodent.
6. What are the conditions for drug substances and formulations intended to be stored:

   (a) Under general conditions (b) In refrigerator (c) In freezer
7. What chemical & pharmaceutical information to be submitted by an applicant for manufacture a new drug already approved in the country?