Curriculum of Ph.D. Program

1. Introduction to the Department

The Department of Clinical Pharmacy & Pharmacology (CPP) was established in 2003 under the Faculty of Pharmacy of University of Dhaka. Since the inception of this prestigious department, it has been offering all the relevant subjects of Clinical Pharmacy & Pharmacology through different graduate programs. The goal of the department is to provide innovative, inter-professional experiences to develop students and pharmacists as integral members of the health care team which will contribute to the health care system both nationally and globally. One year M. Pharm. (Master of Pharmacy) degree is the core program of this department and is offered to the students who have completed five (5) year B. Pharm. Professional (Bachelor of Pharmacy Professional) successfully. Besides M. Phil. (Master of Philosophy) and Ph.D... (Doctor of Philosophy) degree programs are also offered to Pharmacy medical graduates. Faculty members of this department are engaged in extensive research with diverse interests. Main research interests include chemistry and pharmacology of both synthetic and natural products, toxicology, rational use of drugs, cancer biology, molecular and genomic sciences, and drug-protein interaction. The primary goals of the research are to generate and disseminate knowledge to advance patient care, medication safety, disease prevention and treatment, health care cost-effectiveness and quality, and Pharmacy education. Besides the research generated new knowledge are applied to develop, evaluate and innovate health care delivery models, Pharmacy education models, and health policy. The department participate in local, state, national, and global health programs that promote and advocate health improvement, wellness, disease prevention and treatment, and access to health care. The department serves as patient advocates, especially for underserved populations and participate as active leaders of the University and the public at large.

2. Introduction to the Program

Course of study for a Doctor of Philosophy (Ph.D.) in the Department of Clinical Pharmacy & Pharmacology shall extend over a period of three academic years. A student must enroll in the program with thesis. A student must complete all the course works and submit a thesis for the award of Ph.D. degree. The distribution of courses will be decided by the Department. However, the Ph.D. courses in the Department of Clinical Pharmacy & Pharmacology will be conducted under the following general rules and regulations.

- **Title:** Clinical Pharmacy & Pharmacology

- **Duration:** The duration of Doctor of Philosophy (Ph.D.) program will be of three (3) academic years: first year should be comprised of course works. The second and third year should be comprised of thesis. But the registration for the Ph.D. program should be valid four (4) years at the best. Under exceptional circumstances it is possible to submit the thesis after two years. Registration has to be paid every year at the same time until the thesis is submitted. If fails to pay the registration fee on time, it could be paid later with late fees as per rules of University of Dhaka.

  In case of part-time Ph.D. program the registration is valid for five (5) years. In that case thesis can be submitted after four (4) years. If the researcher wants to submit the thesis after three (3) years, it is required to get the approval from the supervisor, the departmental academic committee and finally from the academic council.

The three (3) academic years of the program to be distributed as follows:

1st Year	
Admission Process	04 Weeks
Classes	32 Weeks
Time for preparation of final examination	04 weeks
Course final examination	04 weeks
viva voce	04 weeks
Publication of results	04 weeks
Total	52 weeks
2nd Year	
Thesis (Research)	48 weeks
Thesis Presentation (1st)	04 weeks
Total	52 weeks
3rd Year	
Thesis (Research)	44 weeks
Thesis Presentation (2nd)	04 weeks
Final Thesis Presentation (3rd)	04 weeks
Total	52 weeks
Grand Total (3 Years)	**156 weeks**

❖ Eligibility for Admission:

1) Researcher with M. Phil.

2) Students who have completed four (4) years Bachelor degree and one (1) year Master degree. In case of course system, candidates must have at least either second division oy second class or more than 50% marks in all of their previous degree examinations. In case of semester system, candidates must have at least cGPA 3.5 out of 5.0 or cGPA 3.0 out of 4 in all of their previous degree examinations. But concerned department/ institute/ Ph.D. sub-committee/ faculty can set new eligibility criteria while ensuring the above minimum criteria is fulfilled.

3) Students who have completed three (3) years Bachelor with one (1) year Master. In case of course system, candidates must have at least either second division oy second class or more than 50% marks in all of their previous degree examinations. In case of semester system, candidates must have at least cGPA 3.5 out of 5.0 or cGPA 3.0 out of 4 in all of their previous degree examinations. But concerned department/ institute/ Ph.D. sub-committee/ faculty can set new eligibility criteria

while ensuring the above minimum criteria is fulfilled. Besides the researcher must have work experiences of two years either as a faculty at the Bachelor level or as a researcher or as an employee of a government/ non-government/autonomous organization/ half-autonomous organization. Moreover, the researcher must have two published articles in peer reviewed journals.

- **Admission Process:** For admission into the Ph.D. program, the researchers must show their M. Phil. certificate or the main mark sheets of all previous examinations to get the admission application form. Then the application needs to be filled properly by the applicant and to be submitted for approval by the supervisor, departmental academic committee, Ph.D. sub-committee and faculty committee. Finally the application will be recommended by the Board of Advanced Studies and approved by the Academic Council.

- **General Objective of the Program:** The vision of the Department of Clinical Pharmacy & Pharmacology is to become a center of excellence in Clinical Pharmacy and Pharmacology education, research, consultancy and provision of public services that meet the national, regional and global expectations. The mission of the department is to produce highly trained manpower, skilled professionals and expert health care providers who are able to provide quality health care and consultancy services and carry out research.

3. Structure of Curriculum

The Doctor of Philosophy in Clinical Pharmacy & Pharmacology is awarded by the Department of Clinical Pharmacy & Pharmacology of University of Dhaka (DU) upon the fulfillment of the following requirements:

1. Compliance with the CPP Doctor of Philosophy regulations approved by the academic council.

2. Successful completion of required course works and research as follows:

1st Year: Part- I			
SL No.		**Courses**	**Course Name**
1	**Compulsory**	**Paper- I**	**Clinical Pharmacy and Pharmacology**
2	**Optional (Any one)**	**Paper- II**	**Toxicology and Pharmacovigilance**
		Paper- III	**Preclinical and Clinical Research**
3		**Viva Voce**	
2nd Year: Part- II			
SL No.		**Courses**	
4		**Thesis/Research**	
5		**Presentation (1st)**	**Introduction to research project**
3rd Year: Part- II			
SL No.		**Courses**	
6		**Thesis/Research**	
7		**Presentation (2nd)**	**Progress report**
8		**Final Presentation (3rd)**	**Final Thesis presentation**

4. Assessment System

❖ Mark Distributions:

1st Year: Part- I					
SL No.		**Courses**	**Course Name**	**Marks**	**Pass Marks**
1	**Compulsory**	**Paper- I**	**Clinical Pharmacy and Pharmacology**	**100**	**50%**
2	**Optional (Any one)**	**Paper- II**	**Toxicology and Pharmacovigilance**	**100**	**50%**
		Paper- III	**Preclinical and Clinical Research**	**100**	**50%**
3		**Viva Voce**			
2nd Year: Part- II					
		Courses			
4		**Thesis/Research**		**N/A**	**Decision**
5		**Presentation (1st)**	**Introduction to research project**	**N/A**	**Decision**
3rd Year: Part- II					
		Courses			
6		**Thesis/Research**		**N/A**	**Decision**
7		**Presentation (2nd)**	**Progress report**	**N/A**	**Decision**
8		**Final Presentation (3rd)**	**Final Thesis defense**	**N/A**	**Decision**

❖ Examination System:

The performance of a student in a given course will be evaluated in the following way:

(i) For both the theory and viva voce examination the pass mark is 50% (on an average). Any marks less than 30%, in any course will not be counted. If the researcher remain unsuccessful in the above examination, he may seek a readmission and take sit for the exam. But he can keep the marks for those courses in which he scored more than 50% as he wishes.

(ii) There should be at least 48 classes for a full unit and at least 24 classes for a half unit course. Final theory examination

(iii)If a researcher pass in his/her theory examination but fails in the viva voce, he may participate for the next viva voce examination. But with the consent of the

Academic Council, the department can arrange a viva voce examination for the researcher within the next 3 to 6 months while not waiting for the next year viva voce.

(iv) If any unsuccessful researcher gets less than 50% in only one of the theory or in the viva voce examination, he can take sit in the examination for that particular theory course or the viva voce without readmission as an irregular student as per rules of the university of Dhaka after making the corresponding payments.

(vi) The duration of theoretical course final examinations will be as follows:

Course	Duration of Examination (hours)
Full-Unit Courses	4
Half-Unit Courses	2

(vii) For theoretical course final examinations, there will be two examiners: course teacher will be the first examiner and the second examiner will be from within the department or from any other department of Dhaka University relevant to the subject. In case a suitable examiner is not found from Dhaka University, a teacher from outside Dhaka University may be appointed as second examiner with prior permission from the Vice-Chancellor. Evaluation will be made under the existing rules.

(viii) Thesis will be evaluated as per existing rules of the university with two external examiners from outside the respective Department.

(ix) Oral examination of the Ph.D. students will be conducted by the members of Examination Committee as per existing rules of the university.

- **Grading System:** In the course system students will be graded either as pass or fail based on an average pass marks of 50% as per existing guidance of the University of Dhaka.

- **Leave:** For full-time Ph.D. program, except for the faculties of University of Dhaka, the researcher should join the program with one (1) year leave and the program should be for four (4) years. But researcher can submit the thesis after two (2) years. In that case researcher does not need to take the course works but supervisor may ask the researcher to take courses as need basis. For part-time Ph.D. program the registration is valid for five (5) years and researcher can submit the thesis after four (4) years. But it is possible to submit the thesis after three (3) years if the research activity is satisfactory. In that case, the supervisor and the departmental academic committee should recommend and then Academic Council should approve the thesis submission. At that

situation researcher does not need to take the course works but supervisor may ask the researcher to take courses as need basis. In that case the course work duration will be two (2) years. If course work is not required, the researcher may join the program without taking any leave from the employer organization but verbal permission is required.

- **Placement from M. Phil. To Ph.D. Program:** M. Phil. Researcher, who have completed the theory and viva voce of the 1st year successfully, can apply to transfer from the M. Phil program to the Ph.D. program based on the satisfactory results in second year research. In that case, the application will be initially recommended by the supervisor, departmental academic committee, Ph.D. sub-committee, faculty committee and Board of Advanced Studies. Finally the application will be approved by the Academic Council.

- **Supervisor:** Professors, Associate Professors and Assistant Professors with PhD, can be the supervisors of the M. Phil researchers.

  A supervisor can supervise not more than eight (8) researchers including both M. Phil and Ph.D. students independently or not more than ten (10) researchers in collaboration. If the researcher is a Dhaka University faculty, then he/she will not be counted as a researcher among those ten (10) researcher.

  A Ph.D. researcher can do research under three (3) supervisors- one of whom should be from the Department of Clinical Pharmacy & Pharmacology and other should be from another Department of Dhaka University or from research institute that is accredited by University of Dhaka. But principal supervisor should be from the Department of Clinical Pharmacy & Pharmacology. Not more than one (1) co-supervisor can be selected from institute other than University of Dhaka and should be approved by the academic council.

- **Change of Supervisor**: If a Ph.D. Researcher want to change the supervisor, he/she must collect the specified from form Education-1of Office of Registrar and submit it to the department of Clinical Pharmacy & Pharmacology after filling it appropriately. The application needs to be approved initially by the departmental and faculty academic committees. Later the Board of Advanced Studies and Academic Council should approve the application. In this case both former and proposed supervisors must provide written consent.

- **Change of Title:** If a Ph.D. Researcher want to change the title of the research project, he/she must collect the specified from form Education-1of Office of Registrar and submit it to the department of Clinical Pharmacy & Pharmacology after filling it appropriately. The application needs to be approved initially by the departmental and faculty academic committees. Later the Board of Advanced Studies and Academic Council should approve the application.

❖ Thesis Submission and Time Extension:

a. Ph.D. Researcher should submit the thesis within three (3) year of the publication of 1st year results. If the researcher failed to submit the thesis on time, he/she must collect the specified from for time extension form Education-1of Office of Registrar and submit it to the department of Clinical Pharmacy & Pharmacology after filling it appropriately. The application needs to be approved initially by the departmental and faculty academic committees. Later the Board of Advanced Studies and Academic Council should approve the application.

b. If Ph.D. Researcher failed to submit the thesis within specified time, he/she can apply to the Vice-Chancellor in a blank paper with recommendation from the supervisor and the Chairman of the Department of Clinical Pharmacy & Pharmacology. Vice–Chancellor can extend the deadline to submit the thesis for another six (6) months according to the Syndicate Resolution passed on 6 December, 2001.

❖ **Readmission:** Ph.D. registration is effective for four (4) years. If the registration gets expired, it is possible to register for another four (4) years.

❖ **New Registration:** It is also possible to do a new registration when both the registration and re-registration duration of eight (8) years is expired. But this is only applicable to those researcher who originally registered before the academic calendar of 2007-2008. For new registration in the Ph.D. program, researcher should pay in excess of five thousand taka (5000/-).

❖ **Progress Report:** Ph.D. researcher should continue his/her research work under the supervision of the supervisor and report the progress to the supervisor every six (6) months. Supervisor should report the progress of the Ph.D. student to the Board of Advanced Studies.

❖ **Seminars:** Ph.D. researcher should give a seminar every year in the presence of the academic committee. At least two seminar report along with the recommendations from the supervisor and departmental academic committee should be submitted to the Office of Examination Controller while submitting the final thesis. Final thesis will not be accepted without the seminar reports.

❖ **Fees:** All information regarding the fees of the M. Phil. Program can be obtained from the Office of Accounts Director.

❖ **Admission to Second Year:** M. Phil. researcher should get admission into the second year within one (1) month of publishing the first year results. But they can get admission even after first month at late fee of one taka (1/-) per day for another one (1) month. If the student fails to get admission within the first two (2) months of the publication of the results, he/she can get admitted later with a late fee of two thousand taka (2000/-).

Courses Outline

Course : Paper-I

Course Title : Clinical Pharmacy and Pharmacology

Marks : 100

Introduction:

The role of qualified pharmacists in clinics and hospitals is increasing day by day. Drug therapy in the presence of a clinical pharmacist is more accurate, effective and less expensive. Pharmacists are the experts of drug and the presence of pharmacists in clinical settings decreases the treatment risk arose from adverse drug reaction and reduce hospital stay of patients. A proper education and practice in pharmacology and Clinical Pharmacy is indispensable to play roles as a pharmacist. The students of M. Phil. and Ph.D. should get advanced knowledge to improve their basic ideas in this field and the present course has been designed considering this aspect.

Specific Objectives:

1. To educate the students the recent topic of pharmacology and clinical pharmacy and progress in this field.

2. To promote safe, appropriate and cost effective prescribing and standard treatment for the patient.

3. The students will get advanced knowledge in Drug therapy and diseases and will be able to understand the application and indications of drugs, and causes, pathological aspects and management of several diseases through therapeutic intervention

4. To promote advanced level research activities in the field of Pharmacology and Clinical Pharmacy.

Course Content:

1. **Cancer Biology and Therapy**: Introduction to biology of cancer, anticancer drugs and their mechanisms, molecular mechanism of resistance, Modes of Treatment, Radiotherapy, Chemotherapy, Biological therapy including immunology and gene therapy, Other chemotherapeutic targets including vascular targets, Abnormal tumor physiology, Growth factors, P53, apoptosis and DNA repair, Relapses, metastasis, , carcinogenesis and genetic predisposition, diagnostic tests.

2. **Pharmacogenetics and pharmacogenomics**: introduction, definition, SNPs and other polymorphisms, RFLP, and direct sequencing as methods of studying polymorphisms. Pharmacogenetics of cytochrome P450 e. g. CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP2A6. Role ofNAT2 and CYP2E1 in tuberculosis. Role of Different polymorphisms in lung

Diseases. Methods of studying prominent SNPs using any software, Pharmacogenetics of cancer, Psychiatric disease, receptor etc.

3. **Bioinformatics:** Definition and concepts, Importance of bioinformatics, biological database, primary sequence database, protein sequence database, genome resource web address, multiple sequence alignment, Coiled coil protein analysis, importance of multiple sequence alignment for drug design, Importance of coiled coil peptide for drug design

4. **Neurological disorders**: Mechanism of neuronal damage, Excitotoxicity, Neurodegenerative disorders: A) Parkinson's disease: Biochemical basis, epidemiology, etiology, pathophysiology, clinical findings, treatment and management, psychotherapy, B) Alzheimer Disease: epidemiology, etiology, pathophysiology, clinical findings, treatment and management, C) stroke: epidemiology, etiology, pathophysiology, clinical findings, treatment and management.

5. **Respiratory disorders**: a) Asthma: epidemiology, etiology, pathophysiology, clinical findings, treatment and management of chronic asthma and acute severe asthma; B) Chronic obstructive airway diseases: epidemiology, etiology, pathophysiology, clinical findings, treatment and management, psychotherapy.

6. **Patient Counseling, education and Chronic disease monitoring**: Format of Counseling area, documentation of counseling, benefits and outcomes, counseling of non-prescription and prescription drugs, patient education, patients learning and behavior, components and types of education, monitoring in the community pharmacy, documentation and patient monitoring.

Learning outcomes:

1. The course will enable the students to achieve advanced d knowledge and develop their skills and expertise in pharmacy practice.

2. The course will also improve the research ability of students in this field

3. Students will acquire the knowledge of how to counsel with patients, and safe and effective therapy for particular diseases.

Class Schedule : 48 classes

1. **Cancer Biology and Therapy** : 12 classes
2. **Pharmacogenetics and pharmacogenomics** : 08 classes
3. **Bioinformatics** : 08 classes
4. **Neurological disorders** : 08 classes
5. **Respiratory disorders** : 06 classes
6. **Patient Counseling, education and Chronic disease monitoring** : 06 classes

Assessment system: As per rule of University of Dhaka

References:

1. Good man and Gillmans: The Pharmacological basis of Therapeutics.

2. Pharmacolgy by Rang and Dales

3. Pharmacology by Katzung

4.Clinical pharmacy and therapeutics, E. T. Herfindal, D. R. Gourley and L. L. Hart, fifth edition, wiullams and willkins publications 1992.

5. Clinical Pharmacy and therapeutics. Roger Walker and Cate whittlesea, fifth edition, Churchill living stone, Elsevier punblications 2018.

6.Davisdsons principles and Practises of medicines, N. R.Colleedge, B. R. walker and S. H. Ralston, 23rd Edition, Churchill living stone, Elsevier punblications 2018.

Course : Paper-II

Course Title : Clinical Toxicology and Pharmacovigilance

Marks : 100

Introduction:

Clinical toxicology involves discussion on the clinically significant adverse drug reactions, toxicity effects of various reactive metabolites and other environmental and organ-specific toxicants as well as their clinical management.

Specific Objectives:

The prime objective of this course will be to help students understand the various aspects, scopes and application of clinical toxicology

Course Content:

1. **Basic concept in toxicology**

Introduction to toxicology, classification of toxic agents, characteristics of exposure, spectrum of undesired effects, interaction of chemicals, tolerance, dose response, variation in toxic responses, descriptive animal toxicity tests. Assessment of toxic substances, their impact on health and target organs. Introduction to toxicology, risk assessment and design of toxicity testing. Acute and chronic toxicities. Toxicity study in animal models. Dose-response relationship.

2. **Molecular aspects and mechanism of toxicology**

Cytotoxicity, DNA damage and its repair, mutagenicity and carcinogenicity, Genotoxicity: Mechanism of genotoxicity and non-genotoxic carcinogens. Cell death and apoptosis, nuclear hormone receptor mediated toxicity; peroxisome proliferators and environmental oestrogens. Neurotoxicity, intra-cellular free radicals.

3. **Reactive intermediates and their toxicity**

General Principles, xenobiotic biotransformation by phase I enzymes, phase II enzyme reactions. Types of metabolically generated reactive intermediates and role in drug toxicity. Epoxidation and drug toxicity, N-Oxidation and drug toxicity, toxicity and Sulphur xenobiotics.

4. **Heavy metal and organometallic toxicity**

Sources and diagnosis of lead, arsenic and mercury poisoning. Acute and chronic toxicities of heavy metals, their mechanism of action. Pharmacological and toxicological effects, metabolism and treatment of the poisoning. Heavy metal antagonist: role of EDTA,

dimercaprol and penicillamine in the treatment of heavy metal poisoning, their mode of action and side effects. Spectrum of toxicity effects of insecticides, botanical insecticides, herbicides, fungicides, fumigants, rodenticides.

5. **System/Organ specific and Drug Class Specific ADRs and toxicity**

Types of adverse drug reactions (ADRs); Mechanisms of ADRs and Drug Interactions; ADR reporting; Management of ADRs: Role of Pharmacists; Fatal Medication Errors and ADRs; Target organ toxicity and related ADRs including - Dermatological, Gastrointestinal, Hematological, Hepatic, Renal, Ocular, Neurological and Cardiovascular Spectrum of ADRs.

6. **Environmental and occupational toxicology**

Environmental toxicology: Air and water pollution in perspective, assessing risks associated with air and water pollution, epidemiologic evidence of health effects, pollutants of outdoor ambient air and water polutants, adverse health effect. **Ecotoxicology:** Introduction to ecotoxicology, chemical movement, fate and exposure, biomarkers, endocrine and developmental disruptors, terrestrial and aquatic ecotoxicology, good laboratory practices in terrestrial land aquatic ecotoxicology, modeling and geographic information systems, ecologic risk assessment, environmental toxicology and human health. **Occupational toxicology:** Workplaces, exposures, and standards, occupational diseases, toxicological evaluation of occupational agents, exposure monitoring.

7. **Current Methods of Pharmacovigilance**

Key Definitions and importance; Generic and specific aims; Need and objectives; Passive vs active pharmacovigilance; Prescription–Event Monitoring (PEM); Designing a pharmacovigilance system, Data collection; Data analysis and reporting; Taking actions for improvement; Pharmacovigilance center; Post-marketing surveillance; Spontaneous Reporting; and Pharmacovigilance for Special Populations and Special Product Classes.

Learning outcomes:

The expected learning outcomes of the course will be to enable students in understanding and learning specifically and comprehensively the following -

- The basic concept of clinical toxicology.
- The molecular mechanisms of clinical toxicity and various aspects of clinical toxicity.
- The spectrum of toxicity effects produced by reactive intermediates, heavy metals and to give idea about the clinical treatment and remedial measures for such toxicity.
- Various types and forms of clinically relevant system/organ specific and drug class specific ADRs and toxicity.
- Pharmacovigilance and post-marketing surveillance of marketed products to avoid adverse effects of drugs.

Class Schedule : 48 classes

7. **Basic concept in toxicology** : 06 classes
8. **Molecular aspects and mechanism of toxicology** : 08 classes
9. **Reactive intermediates and their toxicity** : 06 classes
10. **Heavy metal and organometallic toxicity** : 06 classes
11. **System/Organ specific and Drug Class Specific ADRs and toxicity** : 06 classes
12. **Environmental and occupational toxicology** : 08 classes
13. **Current Methods of Pharmacovigilance** : 08 classes

Assessment system: As per rule of University of Dhaka

References:

1. Casarett & Doull's Essentials of Toxicology, Third Edition, by Curtis D. Klaassen and John B. Watkins III.
2. Introduction to Toxicology, Third Edition, by John Timbrell.
3. Toxicological Chemistry and Biochemistry, Third Edition, by Stanley E. Manahan.
4. Principles of Toxicology, Second Edition, by Phillip L. Williams, Robert C. James and Stephen M. Roberts.
5. A Textbook of Modern Toxicology, Third Edition, by Ernest Hodgson.
6. Mann's Pharmacovigilance 3rd Edition, by Elizabeth B. Andrews and Nicholas Moore, Willey Blackwell, 2014.
7. Textbook of Pharmacovigilance, Edition 1/e, by SK Gupta, ISBN 9789350252062, 2011.
8. A practical handbook on the pharmacovigilance of antiretroviral medicines, WHO, 2013.

Course : Paper-III

Course Title : Preclinical and Clinical Research

Marks : 100

Introduction:

Clinical drug research provides the experimental basis for the assessment of efficacy and safety of new therapeutic agents in human beings and other animals. In other words, it allows us to obtain relevant information to use a drug effectively and safely in an individual patient. Clinical research offers important tools for developing and validating new concepts in clinical pharmacology and therapeutics, using both already existing and new biologically active agents. Another aspect, that is growing increasingly, of pre-clinical and clinical research, is to conduct studies to compare different treatment regimens in the pursuit of revealing one that is superior in terms of safety and efficacy. In recent years, significant advancements have been made in clinical drug research with the availability of new pharmacokinetic, pharmacodynamics and clinical methods, sophisticated ethical and quality assurance standards, automated and on-line data management. This course is a 'Fundamentals of Clinical Research' in the literal sense of the word. It provides the students with relevant information about every aspect of drug research in animals and most importantly in human, from the initial research idea to the ultimate publication and with every step in between.

Specific Objectives:

1. The course is designed to cover the all aspects of the planning and implementation of the clinical study and of the analysis, interpretation and publication of results. Therefore, students will get the actual knowledge of acquainting with latest research methodology.
2. The course content will give space to the ethical implications of methodological issues in clinical research.
3. A detailed coverage on legal issues, patenting, regulatory bodies and WHO guidelines has been incorporated in order to face the global challenges for clinical research.
4. The course is intended to learn the basic study design, writing protocols and analyzing the data with suitable methods.

Course Content:

1. **The drug development process:**
   A) **The drug design and pre-clinical development process:** Overview, the research stages, Identification of lead compounds, Molecular modeling, Drug selection: in vitro assays and experimental models, Biological drugs, Pharmacokinetic studies, the development stages: Scaling up from laboratory to industrial preparations, choice of dosage form, toxicological studies
   B) **The phases of clinical development**: Introduction, Phase I, II and Phase III trials, Registration Dossier, Phase IV trials, Project management, the phases of clinical development for Oncology compounds, Accelerating clinical development etc.

2. **Codes, declarations and other ethical guidance:** Ethical framework for biomedical research, The Nuremberg Code, The Declaration of Helsinki, The Belmont report, Regulations for the protection of humans in research in US, International ethical guidance from the council of international organizations, The European community directives on Data protection and clinical trials, Bioethics commissions and research ethics.
3. **Experimental designs:** Fundamental points-observational and experimental studies, Prospective and retrospective studies, Randomized control trials, Nonrandomized control trials, Cross-over designs, Cohort studies, case-control studies, Withdrawal studies, Factorial designs, The randomization process, Fixed allocation randomization-Simple, blocked and stratified, Adaptive randomization procedures-baseline adaptive, response adaptive process, Blindness-unblind, single-blind, double-blind and triple blind, protecting the double blind design-matching of drugs, coding of drugs, official unblinding, inadvertent unblinding
4. **Data management and statistical analysis:** Hypothesis testing, sample size and power, Data collection, problems in data collection, site education and training, data monitoring, data editing, clinical databases, data entry, data quality control/assurance, statistical analysis plan, statistical approach to analysis.
5. **Study participants, Data collection and Quality control**: Considerations, selections, common problems, planning, sources, Conduct, Monitoring, Problems in data collections, minimizing poor quality data, Development of forms, Training and certificates, Quality monitoring, monitoring forms, procedures, Drug handling Audits etc.
6. **Regulatory Approval and Patent:** A) **Regulatory bodies:** Origins of US FDA and its amendments, Drug amendments act of 1962, FDA modernization and Phase IV clinical trials, History of European Medicines Agency, International Conference on Harmonization, Outline of regulatory approval in the United States, Investigational new drugs, IND and common technical documents, Institutional review board, Timeline of FDA approval, Target product profile, Accelerated approval, Refuse of file, Clinical hold, FDA approval letter, FDA feedbacks, process of administering clinical trials. B) **Patents:** History of patenting, outline of the patenting process, types of documents, organization of information in patent, time-line for patenting, provisional patent applications, sources of law for patenting.

Learning outcomes:

1. The course will address the traditional methods of clinical research, beginning from the history to the traditional designs with a focus on clinical trials.
2. It will provide the students with general concepts on ethics and regulatory issues, patenting guidelines and respective authority to conduct a clinical research.
3. The students will get the knowledge of writing study protocols, designing a study, data safety and management issues, monitoring boards and meta-analysis.
4. Understanding the basic practices of clinical research, students will acquire the steps of pre-clinical research to develop a potential lead compound to a drug candidate.

Class Schedule : 48 classes

14. **The drug development process** : 08 classes
15. **Codes, declarations and other ethical guidance** : 06 classes
16. **Experimental designs** : 10 classes
17. **Data management and statistical analysis** : 08 classes
18. **Study participants, Data collection and Quality control** : 08 classes
19. **Regulatory Approval and Patent** : 08 classes

Assessment system: As per rule of University of Dhaka

References:

1. Principles and Practice of Clinical Research. J. I. Gallin and F. P. Ognibene, Second Edition, Academic press, Elsevier publications, 2007
2. Fundamentals of Clinical Trials. L. M. Friedman, C. D. Furberg and D. L. DeMets. Fourth Edition, Springer publications, 2010
3. The Oxford Textbook of Clinical Research Ethics. Emanuel et. al., Oxford university press, 2008
4. Clinical Trials-Study design, endpoints and biomarkers, drug safety and FDA and ICH guidelines, Tom Brody, Second edition, Academic press, Elsevier publications, 2016
5. Handbook for Good Clinical Research Practice (GCP). WHO guidelines, 2005
6. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations. A. Bacchieri and G. D. Cioppa, Springer publication, 2007
7. General and Molecular Pharmacology. F. Clementi and G. Fumagalli, Fourth edition, Wiley Publication, 2015
8. A Guide to Clinical Drug Research. A. Cohen and J. Posner, Second edition, Kluwer Academic Publishers, 2000