M.Sc. Byelaws and Syllabus

Programme Name:	**M.Sc. (CLINICAL RESEARCH)**
Programme Code:	**540**

Academic Session of introduction of the Programme: Session 2021-22

School Name:	**School of Chemical and Life Sciences**
Department Name:	**Centre for Translational and Clinical Research**
Byelaws:	**M.Sc.**

Contents

1.Approval date of Board of Studies (BoS) meeting for the present syllabus.

03-Sep-2021

2. Approval date and Number of Academic Council (AC) Meeting for the present syllabus:

12-oct-2021 and 158th meeting

3. Vision and Mission statements

Vision

Our Mission at Jamia Hamdard is to build world-class capacity for the growing needs of the clinical research industry. We are committed to enriching students with minute details of the clinical trial, to become the future leaders in the clinical research industry.

Mission

M1: Clinical Research and Training

- CTCR will endeavour to organise clinical evaluation of experimental and approved therapies in various clinical settings
- CTCR will train desired healthcare professionals on conducting clinical trials as per Good Clinical Practices. An extensive training in New Drugs and Clinical trial rules 2019 will also be provided by the centre to the desired healthcare professionals

M2: Disease Biology Research

- The research activities of the Centre always have a relevance with respect to the treatment and health technology assessment of the diseases like, cancer, dementia, diabetes etc.
- The futuristic approach is to strengthen the current as well as prospective collaboration with industry and hospitals in order to bring projects from funding agencies.

M3: Evidence based medicine

- CTCR will endeavour to establish partnership with major hospitals to conduct their therapeutic audit and evaluate translation of clinical research findings to patient care.
- CTCR will train healthcare professionals and transmit the skill of therapeutic audit and generate tools to evaluate the implementation of clinical research findings.

M4: Network Meta-analysis (NMA)

- Centre will be focussing on the conduction and publication of NMA as this field currently unexplored in INDIA. It will help national and international policymakers.

4. Program Educational Objectives/Qualification Descriptors

After completion of this academic program, the students will be able to

QD-1: Demonstrate comprehensive knowledge and skills in areas related to clinical research and drug regulatory affairs

QD-2: Apply knowledge and skills required for identifying problems and issues in clinical trial operations, collection of relevant quantitative and/or qualitative data, analysis and evaluation using methodologies in clinical research as appropriate to the subject(s) for formulating evidence-based solutions and arguments

QD-3: Impart disciplinary knowledge and skills of good clinical practices in areas related to clinical research, medical and scientific communications in order to solve complex problems with well-defined solutions.

QD-4: Communicate the results of studies undertaken in the field(s) of clinical research and drug regulations accurately in a range of different contexts using the main concepts, constructs and techniques of the clinical research

QD-5: Demonstrate knowledge and transferable skills in the fields of (clinical research and drug regulations relevant in employment opportunities like clinical research coordinator, medical writer and regulatory specialist in pharmaceutical companies and hospitals based on learned research and development methodologies

Mission statements and their mapping with QDs

	QD1	QD2	QD3	QD4	QD5
M1	3	2	2	2	2
M2	2	2	3	3	2
M3	3	2	2	1	1
M4	3	1	2	3	2

5. Programme Outcomes/Programme Learning Outcomes

At the end of the programme, students will be able to :

PLO 1	apply the knowledge of basic, advanced and applied sciences to solve complex research and industrial problems;
PLO 2	identify, formulate and obtain solutions to the challenging problems in interdisciplinary fields using principles of chemical and life sciences;
PLO 3	design and develop materials or products or processes suitable for applications in agriculture, medicine and environment that will meet the needs of the stakeholders;
PLO 4	conduct investigation on materials and living organisms and execute novel research in chemical and life sciences with proper experimental design and suitable controls;
PLO 5	choose and apply appropriate, analytical techniques and resources to analyze and address complex problems and come up with logical reasoning through integrative problem-solving approaches;
PLO 6	apply reasoning informed by the contextual knowledge to assess day-to-day issues pertaining to agriculture, environment, medicine and society and the incumbent responsibilities relevant to the careers in chemical and life sciences;
PLO 7	evaluate the impact of chemical and life processes in societal and environmental contexts, and demonstrate the knowledge and need for sustainable development;
PLO 8	commit and conform to professional ethics, responsibilities and norms in professional and societal interactions; and
PLO 9	function effectively as an individual, as a member or as a leader in diverse cross-functional teams and multi-disciplinary groups.

Mapping of PLOs with QDs

	QD1	QD2	QD3	QD4	QD4
PLO1	3	2	3	3	2
PLO2	3	3	3	2	1
PLO3	2	3	1	1	2
PLO4	3	1	3	2	2
PLO5	2	2	3	3	1
PLO6	3	3	3	2	2
PLO7	2	2	3	3	3

6. Programme details.

SCHEME AND COURSE STRUCTURE
MSc Clinical Research

Course code			Course Title	Sessional Marks /Internal Assessment	End Semester Marks/ Semester Examination	Min. Marks	Max. Marks	Allotted Credit/ Course Credit
5	**4**	**0**	**SEMESTER I**					

MCR – CFC101	Foundation Course in Clinical Research (4)	25	75	40	100	4
MCR - DCC101	General Pharmacology (4)	25	75	40	100	4
MCR - DCC102	Regulatory Affairs in Clinical Research (4)	25	75	40	100	4
MCR - DCC103	General Pharmacology (PR) (8)	50	150	80	200	8
Any one MCR – DSE 101 MCR – DSE 102	Pharmaceutical Management (2) Clinical Trials in Complementary Medicine (2)	13	37	20	50	2
Any one MCR-GEC101 MCR-GEC102	Biostatistical Methods in Clinical Research (2) Scientific Communication (2)	13	37	20	50	2
MCR – AEC101	Seminar on Drug discovery and development (2)	13	37	20	50	2
				Total= 26		
SEMESTER II						
MCR – DCC201	Advanced Pharmacology-I (4)	25	75	40	100	4
MCR - DCC202	Advanced Clinical Research (4)	25	75	40	100	4
MCR – DCC203	Clinical Research Practicals and Hands-on Training (8)	50	150	80	200	8
Any one MCR – DSE201 MCR – DSE 202	Pharmacoepidemiology and Pharmacoeconomics (2) Intellectual Property Rights and Patenting (2)	13	37	20	50	2
Any one MCR – GEC201 MCR – GEC202	Recent advances in Public Health (2) Health and Human Rights (2)	13	37	20	50	2
Any one MCR – SEC01	Medical Writing (2)	13	37	20	50	2

MCR – SEC02 MCR – SEC03	Health Communication (2) Tropical Medicine (2)					
					Total= 22	
SEMESTER III						
MCR - DCC301	Advanced Pharmacology-II (4)	25	75	40	100	4
MCR DCC-302	Clinical Trials Design (4)	25	75	40	100	4
MCR - DCC303	Clinical Trials Practicals and Hands-on Training (8)	50	150	80	200	8
Select any two MCR – DSE301 MCR-DSE302 MCR – DSE303	Clinical Trial Operations (2) Pharmacovigilance (2) Medical Coding (2)	13 13	37 37	20 20	50 50	2x2=4
any one MCR – GEC301 MCR – GEC302	Social medicine and community health (2) Research Methodology (2)	13	37	20	50	2
Any one MCR – SEC01 MCR – SEC02 MCR – SEC03	Medical Writing (2) Health Communication (2) Tropical Medicine (2)	13	37	20	50	2
					Total= 24	
SEMESTER IV						
MCR - DCC401	Dissertation (20)	125	375	200	500	20
					Total= 20	

7. Rules and Regulations of the Programme

1.Programme : Master of Science (M. Sc.)

M.Sc. in the following subjects:

i) Biochemistry
ii) Biotechnology
iii) Botany
iv) Chemistry
v) Toxicology
vi) Clinical Research

Each programme shall be denoted by three digit code as follows :

a)	Biochemistry	507
b)	Biotechnology	508
c)	Botany	509
d)	Chemistry	510
e)	Toxicology	511
f)	Clinical Research	540

Each course of programme shall be given a course number which shall be preceded by three abbreviation as follows :

a)	Biochemistry	MBC
b)	Biotechnology	MBT
c)	Botany	MBO
d)	Chemistry	MCH
e)	Toxicology	MTX
f)	Clinical Research	MCR

These all are full time regular courses.
The Core, discipline Centric and Open elective Courses shall be abbreviated as follows :

Core Course	:	CC
Discipline Centric Elective	:	DCE
Open Elective	:	OE

These abbreviations shall be preceded course number of each course of programme.
During an academic year, a candidate who is enrolled in the M.Sc. Programmes, shall not be allowed to enroll for any other full-time programme of study and shall not appear in any other examination of a full time course of this or any other university.

2. Duration : Two Years of Four semesters (two in each year) designated as under:

1st Semester - July-Dec of 1st year
2nd Semester - Jan-June of 1st year
3rd Semester - July-Dec of 2nd year
4th Semester - Jan-June of 2nd year

Teaching days in each semester shall be not less than **90 days**.

Medium of instruction and examinations: English

3. Eligibility of Admission:

All candidates seeking admission to any of the above M.Sc. programmes must appear in the Entrance Test or Admission Counselling conducted by Jamia Hamdard. Also, the candidates should fulfill the following qualifications for admission to as mentioned below for each programme :

M.Sc. Clinical Research : Candidates with any of the following qualifications from a university recognized by Jamia Hamdard, with at least 45% marks in aggregate, shall be eligible for admission to this programme: MBBS / BDS / BAMS / BUMS / BVSc./B.Pharm/BSc-Nursing/BOT/ BPT/ BSc-Medical Lab. Techniques/BSc with Biochemistry/ Biotechnology/ Microbiology/ Zoology/ Bioinstrumentaion or any other life sciences/ allied health sciences.

4. Course Structure:

a) Foundation course will be of 4 credits (100 marks) and 64 hours duration. The internal assessment (Sessional Tests) shall be of 25 marks while the final examination will be of 75 marks. There will be three Sessional tests. In each sessional test question from all the units will form the question paper.

b) There shall be not less than **twenty credits** of courses in each semester.

c) A project of not less than 20 credits may be prescribed in the course structure in 4th semester in place of theory papers or theory papers and project. The project work may involve experimental, clinical work, review article and drug profile on a specified topic.

d) Though for project work the topics shall be given in advance, the credits assigned for the project work shall be awarded at the end of 4th semester. For project work, the Head of the Department shall call a meeting of all the teachers of the Department and assign appropriate number of students to each teacher to act as the supervisor for project work. The student in consultation with the supervisor shall select a topic for the project work and inform the Head of the Department.

5. Attendance

a) All Students must attend every lecture and practical class. However, to account for unforeseen contingencies, the attendance requirement for appearing in the semester examinations shall be a minimum of 75% of the classes prescribed for each course.

b) In order to maintain the attendance record of a particular course, a roll call will be taken by the teacher in every scheduled lecture and practical class. For the purpose of attendance, each practical class will count as one attendance unit, irrespective of the number of contact hours. Attendance on account of participation in the prescribed and notified activities such as, NCC, NSS, Inter University sports, educational tours/field work, shall be granted provided the participation of the student is duly verified by the officer-in-charge and is sent to the Head of the Department within two weeks of the function/activity, etc.

c) The teacher shall consolidate the attendance record for the lectures and practicals at the end of each month and submit to the Head of the Department. At the end of the semester, the teacher shall consolidate the attendance record for the whole semester and submit it to the Head of the Department. The statement of attendance of students shall be displayed by the Head of the Department on the Notice Board. A copy of the same shall be preserved as record. Attendance record displayed on the Notice Board shall deemed to be a proper Notification for the students and no individual notice shall be sent to any student.

d) If a student is found to be continuously absent from the classes without any information for a period of 30 days, the concerned teacher shall report the matter to the Head of the Department who will report the matter to the Registrar through Dean of the School for appropriate action that will include striking off the name of such student(s) from the rolls. Such a student may, however, apply for re-admission within 7 days from the date of issue of the notice of striking off the name of such student(s) from the rolls. The request for re-admission may be considered by the Dean of the School . Such a student shall not be eligible for re-admission after the prescribed period of 7 days. The re-admission shall be effected only after the payment of prescribed re-admission fee.

e) **A student with less than 75% attendance in a course in a semester shall be detained from appearing in the semester examination of that course. The Dean of the School may consider application for condoning up to 5% of attendance on account of sickness, provided the medical certificate, duly**

certified by a Registered Medical Practitioner/Public Hospital had been submitted in the office of the Head of the Department at the time of rejoining the classes immediately after the recovery from illness. The HoD shall forward such cases along with all related documents to the Dean. The cases of students with less than 70% attendance may be forwarded to the Vice-Chancellor through Dean for considering these case to further condone the attendance as special case.

f) A student detained on account of shortage of attendance in any semester shall be re-admitted to the same class in the subsequent academic year on payment of prescribed fees applicable in that year to complete the attendance requirement of that course.

6. Internal Assessment :

The Internal Assessment marks will constitute upto 25% of the total marks allotted to a course. For awarding Internal Assessment marks, there shall be three Sessional tests for each course in a semester. First sessional test shall be taken in the beginning of the session, 2nd after two months of the session, and the 3rd sessional test 15 days before the commencement of the final semester examination.

7. Semester Examination:

Each credit should be given weightage of minimum 25 marks. Compulsory Foundation course shall be of 04 credits (100 marks). There shall be not less than two theory courses and one lab course in each semester, except 4th Semester. The detailed contents of the courses of studies shall be prescribed by respective Board of Studies and shall be reviewed regularly.

A student who fails in theory papers of end semester examination may be given a chance to appear in 3 papers in Makeup examination to clear those papers. In no case shall it be allowed to the students who abstain from appearing in the semester examination. Students who are detained due to shortage of attendance shall not be allowed to appear in the Makeup examination.

Semester examination shall be held at the end of each semester as per schedule given in the Academic Calendar of the School .

Upto maximum of seven days preparatory holidays may be given to the examinees before the start of the semester examinations.

The question paper for semester examinations, shall be set either by the external examiner or an internal examiner. The Board of Studies of a department shall draw a panel of name of examiners, both internal and external, for approval by the Vice chancellor. **If the external examiner is unable to send the question paper by the deadline set by the examination branch of the University, the Head of the Department after consultation with the examination branch shall get the paper set internally by a School .** The papers set by the examiners can be moderated in consultation with the teacher who taught that course. Teachers appointed on contractual basis with appointment of less than one academic session, and temporary as well as ad-hoc teachers may not ordinarily be appointed as examiners. All such teachers, however, will be expected to assist in the practical examination.

The question paper shall have five questions. There shall be one question from each of the 4 units of the course and one question shall contain objective type/short answer questions covering all the units of the course. The candidate shall have to answer all the five questions. There shall, however, be internal choice within a unit. The choice shall be given by setting alternative questions from the same unit. The question paper should be such that it covers all the topics of that course.

The duration of the semester examination of a theory course shall be Three hours. Practical exams of a lab course shall be of at least four hours duration. The practical examination shall be conducted by an external and an internal examiner and assisted by other teachers.

For projects, **each student shall submit three typed bound copies of his/her project work to the supervisor(s)** by the end of the 4th semester. A student shall not be entitled to submit the project report unless he/she has pursued project work during 4th semester under the guidance of a duly appointed supervisor(s). The report shall embody the candidates own work and an up-to-date review of the subject area. The write-up shall detail a critical assessment of the subject area and indicate in what respect the work appears to advance the knowledge of the subject concerned and future course of investigation required.

The project report shall be examined by a Board of Examiners and the student shall have to appear for viva-voce. The Board of Examiners shall consist of the following:

- An external examiner
- Head of the Department

- A senior teacher of the Department
- Concerned Supervisor(s)

The Board shall examine the project report of all the students, **conduct the viva-voce and award marks for the project and viva-voce. All other teachers of the department will also be invited by the Head of the Department to be present during the examination.** In case a student fails to secure the minimum pass marks, he/she may be asked to appear in the viva-voce again, or he/she may be asked to revise the project report in the light of the suggestions of the examiners and resubmit. For this, he/she will have to enroll as an ex-student in the next session. A resubmitted project report will be examined as above and viva voce shall be conducted along with other students.

8. Choice Based Credit System (CBCS)

Definitions of key words:

a) **Academic Year:** Two consecutive (one odd + one even) semesters constitute one academic year.
b) **Choice Based Credit System (CBCS):** The CBCS provides choice for students to select from the prescribed courses (core, elective or minor or soft skill courses).
c) **Course:** Usually referred to, as 'papers' is a component of a programme. All courses need not carry the same weight. The courses should define learning objectives and learning outcomes. A course may be designed to comprise lectures/ tutorials/laboratory work/ field work/ outreach activities/ project work/ vocational training/viva/ seminars/term papers/assignments/ presentations/ self-study etc. or a combination of some of these.
d) **Credit Based Semester System (CBCS)**: Under the CBCS, the requirement for awarding a degree or diploma or certificate is prescribed in terms of number of credits to be completed by the students.
e) **Credit Point:** It is the product of grade point and number of credits for a course.
f) **Credit:** A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.
g) **Cumulative Grade Point Average (CGPA):** It is a measure of overall cumulative performance of a student over all semesters. The CGPA is the ratio of total credit points secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed up to two decimal places.
h) **Grade Point:** It is a numerical weight allotted to each letter grade on a 10-point scale.
i) **Letter Grade:** It is an index of the performance of students in a said course. Grades are denoted by letters O, A+, A, B+, B, C, P and F.
j) **Programme:** An educational programme leading to award of a Degree, diploma or certificate.
k) **Semester Grade Point Average (SGPA):** It is a measure of performance of work done in a semester. It is ratio of total credit points secured by a student in various courses registered in a semester and the total course credits taken during that semester. It shall be expressed up to two decimal places.
l) **Semester:** Each semester will consist of 15-18 weeks of academic work equivalent to not less than 90 actual teaching days. The odd semester may be scheduled from July to November and even semester from December to April.
m) **Transcript or Grade Card or Certificate :** Based on the grades e:rrned, a grade certificate shall be issued to all the registered students after every semester. The grade certificate will display the course details (code, title, number of credits, grade secured) along with SGPA of that semester and CGPA earned till that semester.

9. Semester System and Choice Based Credit System

The semester system accelerates the teaching-learning process and enables vertical and horizontal mobility in learning. The credit based semester system provides flexibility in designing curriculum and assigning credits based on the course content and hours of teaching. The choice based credit system provides a 'Cafeteria' type approach in which the students can take courses of their choice, learn at their own pace, undergo additional courses and acquire more than the required credits, and adopt an interdisciplinary approach to learning.

10. Types of Courses :

Courses in a programme may be of three kinds according to CBCS : Core, Elective and Foundation.

a. Core Course:- There may be a Core Course in every semester. This is the course which is to be compulsorily studied by a student as a core requirement to complete the requirement of a programme in a said discipline of study.

b. Elective Course:- Elective course is a course which can be chosen from a pool of papers. It may be:

- Supportive to the discipline of study.
- Providing an expanded scope.
- Enabling an exposure to some other discipline/domain.
- Nurturing student's proficiency/skill.

An elective may be "Open Elective" focusing on those courses which add generic proficiency to the students. An elective may be "Discipline centric" or may be chosen from an unrelated discipline. It may be called an "Open Elective."

c. Compulsory Foundation Course:-

Compulsory Foundation course is the courses based upon the content that leads to Knowledge enhancement. It is mandatory for all students. Elective Foundation courses are value-based and are aimed at man-making education.

11. Classification of Result :

a) Two methods -relative grading or absolute grading- have been in vogue for awarding grades in a course. The relative grading is based on the distribution (usually normal distribution) of marks obtained by all the students of the course and the grades are awarded based on a cut-off marks or percentile. Under the absolute grading, the marks are converted to grades based on pre-determined class intervals. To implement the following grading system, the colleges and universities can use any one of the above methods.

b) Following grading system with 10 point scale shall be followed to represent performance of students in the examination:

Grades and Grade Points :

Letter Grade	Grade Point	Marks
O (Outstanding)	10	90 – 100
A+ (Excellent)	9	80 – 89
A (Very Good)	8	70 – 79
B+ (Good)	7	60 – 69
B (Above Average)	6	50 – 59
C (Average)	5	45 – 49
P (Pass)	4	40 – 44
F (Fail)	0	Less than 40
AB (Absent)	0	

Earned Credits (EC) :

The credits for the courses in which a student has obtained P (minimum passing grade for a course) or a higher grade in the semester exam shall be counted as credits earned by him/her. Any course in which a student has obtained ‘F’ or ‘AB’ grade shall not be counted towards his/her earned credits.

12. Computation of SGPA and CGPA :

Following procedure to compute the Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA):

a) SGPA (Semester Grade Point Average) shall be awarded on successful completion of each semester.

b) CGPA (Cumulative Grade Point Average), which is the Grade Point Average for all the completed semesters at any point in time shall be awarded in each semester on successful completion of the current semester as well as all of the previous semester. In 1st semester, CGPA is not applicable.

13. Calculation of SGPA and CGPA of A Student in a Semester :

$$\text{SGPA} = \frac{\Sigma\ (\text{Earned Credits X Grade Point})}{\Sigma\ (\text{Total Course Credits in a Semester})}$$

$$\text{CGPA} = \frac{\sum_{j=1}^{m} (\text{Earned Credits X grade point})}{\sum (\text{Total Course Credit in a Semester})}$$

Where m is the number of semesters passed

14. Promotion :

a) Promotion from 1st semester to 2nd semester and from 3rd semester to 4th semester shall be automatic.

b) A student shall be promoted to the 3rd semester of the programme if he/she has passed in each theory and practical courses separately of 1st and 2nd semesters. Provided that a student may carry over a maximum of 8-9 credits (equivalent to two-three theory papers, which may be of 3 or 4 credits each) of courses uncleared, to the 3rd semester). A candidate will be given a total number of 2 attempts, inclusive of the first attempt, to clear the papers in which he/she fails. For such students, promotion to the next higher class will be considered subject to rules relating to passing the 1st and 2nd semester examinations within two academic years. Award of degree shall be subject to successfully completing all the requirements of the programme of study within four years from admission. A student who fails in theory papers of end semester examination may be given a chance to appear in 3 papers in Make-up examination to clear those papers. In no case shall it be allowed to the students who abstain from appearing in the semester examination.

c) Candidates who are unable to appear in the examination because of serious illness at the time of examinations may be given another chance. The request has to be processed through the Head of the Department to the Vice Chancellor. The Vice chancellor may look into the merit of the case and decide accordingly.

15. Classification of Successful Candidates :

The result of successful candidates who fulfill the criteria for the award of M. Sc. shall be classified after the 4th semester, on the basis of his/her CGPA of all the four semesters.

Classification shall be done on the basis of following criteria:

a) He/She will be awarded “Ist Division” if his/her final marks are greater than or equal to 60% in all the semester examinations in the first attempt.
He/she will be awarded “Ist Division” if his/her final CGPA is 7 or above

b) He/She will be awarded “2nd Division” if his/her final marks are greater than or equal to 50% but less than 60% in all the semester examinations in the first attempt.
He/she will be awarded “2nd Division” if his/her final CGPA is 6 or above but less than 7

c) He/She will be awarded “Pass” if his/her final marks are greater than or equal to 40% but less than 50% in all the semester examinations in the first attempt.
He/She will be awarded “Pass” if his/her final CGPA is 5 or above but less than 6.

d) He/She will be treated as “fail” if his/her final marks are less than 40% in all the semester examinations in the first attempt.
He/She will be treated as “fail” if his/her final CGPA is less than 5

16. Span Period :

a) 1st and 2nd Semester Exams: Within two years from the first admission to the programme
b) All requirement of M. Sc. degree within a total period of four years from the date of their first admission.

17. Improvement :

A candidate who wishes to improve the previous performance will be allowed to do so as per the following regulation :

a) A student shall be allowed only once to reappear in the semester examination of up to four theory courses along with regular students of that semester to improve upon the previous performance. The examination fee charged from such candidates shall be double the current examination fee.
b) Such a student shall inform the Head of the Department in writing of his/her intention to improve the performance two months before the date of semester examination is to be held. Only the candidates who have attained at least C grade shall be eligible for improvement of performance.
c) If the student improves the performance, he/she shall be required to submit the earlier mark-sheet/degree. A new mark-sheet and degree shall be issued. The new mark-sheet/degree shall bear the year in which the student improved the grade.
d) In case the grade obtained in improvement is lower than the one obtained earlier, the higher grade shall be retained.

18. Consolidated Mark sheet :

On successful completion of the course, a consolidated marksheet consisting of marks of all the Semesters shall be issued to the students by the Examination Section.

19. Award of Gold Medal :

Gold Medal will be given to the toppers of each course. However, only the overall topper in all the disciplines of any course will be given Gold Medal by the Chief Guest in the Convocation. Criterion for giving the Gold Medals will be percentage of marks. Therefore, students with highest % of Marks will be given the Gold Medal in each discipline of a course.

7. COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR - CFC101** Title of the Course: **Foundation Course in Clinical Research**

L-T-P: L=64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO1	Identify and explain the structure and functions of different body system (Evaluate level)
CLO2	Apply to clinical scenarios the concepts and knowledge of the general terminology, cell structure and function, histology, gross anatomy, and physiology of several organ systems (Analyze level)
CLO3	Research and critically evaluate various sources of information related to these systems, in order to discern reliable scientific information from unsourced information and pseudoscience. (Understand level)
CLO4	Evaluate information on human health and medical research related to its social, environmental, and ethical implications as a responsible member of society. (Understand level)
CLO5	Demonstrate how these human organ systems are interrelated to apply a holistic approach to human health. (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	1	1	2	2	1	3	1	1	3	1	1	3	3
CLO2	2	3	3	3	2	3	2	2	1	1	2	3	3
CLO3	3	3	3	3	3	3	3	3	3	2	3	3	3
CLO4	3	3	3	3	3	3	3	3	1	3	2	3	3
CLO5	3	3	3	3	3	3	3	2	2	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I: Anatomy and Physiology of organ system of human body – I (16 hours)
Basics of biological organization: Cell and organelles, tissue, organs and their interrelationship, musculoskeletal system, bone
Nervous System: General overview of Autonomic nervous system (ANS). Mechanism of neurotransmission. Introduction to some common CNS disorders, their diagnostic tests
Cardiovascular and Hematopoietic System: Organizational and Functional aspects. Introduction to some common CVS disorders, their diagnostic tests
Respiratory System: Structure of lung, Role of different cells, lung aerodynamics, gas exchange and assessment of lung functions. Introduction to some respiratory disorders: diagnostic tests
UNIT II: Anatomy and Physiology of organ system of human body – II (16 hours)
Gastrointestinal System: The digestive system: Organizational and Functional aspects. Introduction to different organs of digestive system. Hepatic functions and their assessment (liver function test, LFT).Introduction to some common GI disorders: diagnostic tests.

Genitourinary system: Structure of kidney and mechanism of excretion. Kidney function tests. Introduction to some common renal disorders: diagnostic tests
Unit III : Anatomy and Physiology of Organ System of Human body-III (16 hours)
Immune System: Organization of various components of immune system, cellular organization and cytokines. Introduction to some common diseases: diagnostic tests
Endocrine System and reproductive system: General overview of endocrine system and reproductive system. Introduction to some common hormones, their disorders, diagnosis.
UNIT IV: Basics of pharmaceutical technology (16 hours)
Basics of pharmaceutical technology: Different dosage forms, physicochemical properties of a dosage form, understanding of partition coefficient, stability testing
Active pharmaceutical ingredients

Reference Books:

1. Ross and Wilson Anatomy and Physiology in Health and Illnessby Waugh A Churchill Livingstone; 12 edition
2. Anatomy & Physiology Workbook, 2014 India Editionby Gerard J. Tortora and Bryan Derrickson Wiley; 13th Edition
3. Principles of Pharmacology by HL Sharma and KK SharmaParas Medical Publisher;11th edition

Teaching-Learning Strategies in brief

1. The learning abilities are incorporated with the help of visualization technology enriched with the advanced text
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Assessment methods and weightages in brief

The performance of the student in each paper will be evaluated both continuously (Internal Assessment) and at the end of semester (Semester Examination). 25% marks for each theory paper will be allocated for internal assessment and 75% marks will be kept for semester examination at the end of each semester

COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – DCC 101** Title of the Course: General Pharmacology

L-T-P: P-64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Differentiate between different types of drugs, routes of administration and receptors (Analyze level)
CLO-2	Interpret different pharmacokinetic parameters and apply these in the interpretation of clinical data (Analyze level)
CLO-3	Classify mechanisms of pharmacodynamics through which various drugs act (Understand level)
CLO-4	Differentiate between different adverse drug reactions and drug interactions (Analyze level)
CLO-5	Understand neurohumoral transmission and autonomic nervous system (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	3	2	3	3	3	1	3	11	2	1	3
CLO2	3	3	3	2	3	3	3	1	3	1	3	3	3
CLO3	2	3	3	1	2	3	3	2	3	1	2	1	3
CLO4	3	3	3	2	3	3	3	1	3	2	1	1	3
CLO5	3	3	3	3	3	3	3	2	3	1	2	1	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I: Introduction to Pharmacology	**(12 hours)**
	- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non-competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
UNIT-II – Pharmacokinetics	**(10 hours)**
	Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination
UNIT III – Pharmacodynamics	**(26 hours)**
	Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. Adverse drug reactions. c. Drug interactions (pharmacokinetic and pharmacodynamic)

UNIT IV-Autonomic Nervous System		(16 hours)
	General concepts- neurohumoral transmission, neurotransmitters, Cholinergic pharmacology, Adrenergic pharmacology	

Reference Books:

3.Principles of Pharmacology by HL Sharma and KK Sharma: Paras Medical Publishers, New Delhi;6th edition

1.Basic and Clinical Pharmacology by Bertram G. Katzung and Anthony J. Trevor Mc Graw-Hill;12th Edition

2. Essentials of Medical Pharmacologyby K.D. Tripathi Jay Pee Medical; Seventh edition

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – DCC 102** Title of the Course: Regulatory Affairs in Clinical Research

L-T-P: L-64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Comply with different regulatory guidelines for the conduction of clinical trial. (Create Level)
CLO-2	Compare different regulatory guidelines for clinical trial (Understand Leve;)
CLO-3	Assemble the documents used for filing of drugs (Create level)
CLO-4	Explains the historical evolution of different regulatory bodies (Evaluate level)
CLO-5	Explains the importance of GCP, GLP and GMP for medicines (Evaluate level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	2	1	1	3	1	3	3	3	3	3	3	1	3
CLO2	2	2	2	3	1	3	1	3	2	2	3	1	3
CLO3	2	3	2	3	2	3	3	3	2	1	3	1	3
CLO4	2	2	1	3	1	3	1	3	2	2	3	2	3
CLO5	2	2	3	3	1	3	1	3	2	2	3	2	3

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Detailed Syllabus:

UNIT I- Introduction of Evolution of regulatory control (19 hours)	
1	Evolution of Regulatory controls: An international comparison Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki, International Conference on Harmonization (ICH), National Institute of Health and Clinical Excellence (NICE)
UNIT II – Regulatory aspects of different regions (19 hours)	
	Investigational New **Drug** (IND), New **Drug** Application (NDA), Abbreviated New **Drug** Application (**ANDA)**, Paper NDA, Market authorization holders (MAH), its procedures, Post-marketing Surveillance (PMS) , Regulation of medical devices , Regulation of vaccines, Safety Report filing ,Regulation of prescription drugs and non prescription drugs, Regulatory system in Japan, Australia and Brazil
UNIT III Regulatory Guidelines (20 hours)	
	Good Clinical Practice **(**GCP)guidelines, Overviews of GLP, Schedule Y of Indian Drugs and Cosmetic Act., Basic regulation of BA/BE studies, Introduction to European Medicines Agency (EMEA), Organisation for Economic Co-operation and Development (OECD),Agencia Nacional de Vigilancia Sanitaria(ANVISA),Therapeutic Goods Administration (TGA),Regulation of Traditional and Herbal Remedies
UNIT IV- Common Technical documents: Format of dossier **(6 hours)**	

Reference Books:

1. Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
2. Principles and Practice of Clinical researxch by John I, Gallin;Academic Press Inc;3rd Edition
3. Regulatory guidelines ICH, USFDA, Indian GCP, EMEA etc

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – DCC 103** Title of the Course: General Pharmacology (Practical)

L-T-P: P-128 Credits: 8
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Extract and categorize the patient's demographic data from the available literature (Create level)
CLO-2	Create a case report of different diseases (Create level)
CLO-3	Differentiate between different routes of administration and animal models of the diseases (Analyze level)
CLO-4	Create a scientific presentation for the research papers of clinical trials done on various drugs (Create level)
CLO-5	Prepare a scientific document related to pharmacology of different diseases (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO1	3	1	3	2	1	3	2	1	3	3	2	3	2
CLO2	2	2	3	2	1	3	1	2	3	3	3	2	3
CLO3	2	2	3	3	1	3	3	2	3	2	2	2	3
CLO4	2	3	3	3	1	3	1	2	3	3	3	3	3
CLO5	3	3	3	3	1	3	3	3	3	3	3	3	3

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Detailed Syllabus:

UNIT I : Introduction to clinical practice (32 hours)	
	Patient's history and demographics Medical record keeping Preparation of Case reports of different diseases (central nervous system, cardiovascular system,endocrinological disorders, and cancer)
UNIT-II: Introduction to pre-clinical techniques (32 hours)	
	Demonstration of routes of exposure/administration of drugs Demonstration of some non – invasive techniques in preclinical screening of drug
UNIT III : Research Paper presentation (32 hours)	
	Scientific presentations of Research Papers on Randomized Controlled Trials of different diseases using ICT Summary preparation of the Research Papers presented above and submission
UNIT IV: Review Paper Presentation (32 hours)	
	Scientific Presentation of a Review/Topic related to the subject selected by the candidate using ICT

	Summary preparation of the work presented above and submission

Reference Books:
NA

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – DSE 101** Title of the Course: Pharmaceutical Management

L-T-P: L-32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Outline the importance of marketing in pharmaceutical industry (Understand level)
CLO-2	Differentiate between sales and marketing of drugs (Analyze level)
CLO-3	Describe marketing strategies used to increase profit of company (Evaluate level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO1	2	1	2	3	1	3	2	3	3	3	2	1	3
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CLO3	3	3	3	3	2	3	2	3	3	3	2	3	3

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Detailed Syllabus:

UNIT I Pharmaceutical marketing: (16 hours)
Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; Analyzing the Market; Role of market research.
UNIT-II Product decision& sales: (16 hours)
A. Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry B. Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Reference Books:

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi

2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – DSE 102** Title of the Course: Clinical Trials in Complementary Medicine

L-T-P: L-32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Design clinical trials documents such as protocol, case report form, informed consent documents (Create level)
CLO-2	Appraise the responsibilities of stakeholders in clinical trials (Understand level)
CLO-3	Assess the handling of termination of trials (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO3	1	2	2	3	1	3	2	2	3	3	3	3	3

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Detailed Syllabus:

Unit I: Conduction of clinical trial (16 hours)	
	Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection,The roles and responsibilities of the following in clinical trial: Sponsor, institution, Clinical Trial Coordinator: Clinical Investigator Documents required at site, Site initiation and conduct activities: Protocol, Case Report Form (CRF), Informed consent documents (ICD), Investigator brochure, Clinical trial agreement, ethics Committee and regulatory approval, site-initiation visits
Unit II:Documents for clinical trial (16 hours)	
	Recruitment, Investigational Product (IP)/Investigational Medicinal Product (IMP)/Pharmacy file receipt and storage, clinical trial site master file, Databases, Standard Operating Procedures (SOPs), Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections independent data monitoring activities, Contingency planning to prepare for unexpected situations.

	Suspending and premature termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, Clinical study report, submission to ethics committee and regulatory agency, publication of result

Reference Books:

1.Principles and practice of Clinical Research by John. I Gallin.; Academic Press;3rd Edition
2.Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press; Ist Edition
3.Guidelines like GCP, USFDA, EMEA, Indian GCP etc.

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR-GEC 101** Title of the Course: Biostatistical Methods in Clinical Research

L-T-P: L-32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Explain the bio-statistical principals to create the hypothesis and design of clinical trials (Evaluate level)
CLO-2	Identify the nature of data generated in clinical trials (Analyze level)
CLO-3	Apply statistical tests to data generated in clinical trials and interpret data (Analyze level)

Mapping of Course Learning Outcomes (CLOs) with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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Detailed Syllabus:

UNIT I: Statistical analysis (16 hours)
Types of data and its analysis (categorical *vs* quantitative), paired and unpaired test, Organization of data, Distribution of data and calculation of central tendencies, Confidence interval, standard deviation (SD), standard error (SE), Regression and correlation Comparison of data between different groups-using null hypothesis and test of significance (t-test, paired t-test, Analysis of variance (ANOVA), Analysis of covariance (ANCOVA), Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis.
UNIT II: Softwares for statistical analysis (16 hours)
Use of software in Statistical analysis, Intention-to-treat (ITT) and Per-protocol (PP) and Treatment-received (TR) analyses of results in clinical research, Sample size calculation, Advanced topics in biostatistics related to design and analysis of randomized clinical trials Introduction to common software packages used in clinical research (e.g. Statistical Analysis System, SAS or Oracle software**)**

Reference Books:

1.Biostatistics for Medical, Nursing and Pharmacy Students.by A. Indrayan and L. Satyanarayana;Prentice-hall Of IndiaPvt Ltd ;2009 Edition

2.Biostatistics: The Bare Essentialsby Geoffrey R. Norman and David L. Streiner; McGraw Hill; 3RD Edition
3.Methods in Biostatistics for Medical Students & Research workers by B.K Mahajan; Jaypee;7th Edition

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR-GEC 102** Title of the Course: Scientific Communication

L-T-P: L-32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Differentiate between types of scientific communications (Analyze level)
CLO-2	Appraise the literature critically to prepare research papers, posters, review articles etc. (Create Level)
CLO-3	Discover the sources of scientific information (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO3	2	3	3	2	2	3	3	3	1	1	3	2	3

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Detailed Syllabus:

Unit I: General Concepts (16 hours)
Need for scientific communication, Relevance and use of science communication - Public Understanding of Science (PUS) Sources of scientific information – books, scientific reports, scientific journals, magazines, leaflets, speeches, seminars, press releases, databases, encyclopedias on science etc.
Unit II: Scientific writing (16 hours)
Writing journal article, proposal writing, usage of graphics and formatting Grammatical error, Hypothesis testing Proposal writing: strategies of developing good proposal, Publishing and peer review, Communication in the era of new media, Preparing oral and poster presentations

Reference Books:

1. A practical guide to quality management in clinical trial research by Graham D, Ogg;CRC Press ;2ND Edition
2. Clinical Trial Audit preparation: A guide for Good clinical practice by VM Madzarevic; ABC of Complementary medicine;2nd edition
3. Regulatory guidelines like ICH, USFDA, Indian GCP etc

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program M.Sc. Clinical Research

Course Code: **MCR – AEC 101** Title of the Course: Seminar on Drug discovery and development

L-T-P: P-32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Identify the novel drug discovery phases for different diseases (Analyze level)
CLO-2	Prepare a descriptive scientific document pertaining to drug discovery process (Create Level)
CLO-3	Design a printable document using ICT (Create Level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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Detailed Syllabus:

UNIT I : A seminar presentation using ICT tools can be prepared on (8 hours)	
1	Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase,
UNIT-II: Introduction to clinical trial (8 hours)	
	Clinical trial phase, phases of clinical trials and pharmacovigilance.
UNIT III : Drug discovery and development (8 hours)	
	New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics,
UNIT IV-	Concept of generics, Generic drug product development. **(8 hours)**

Reference Books:

1. Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene 9
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

Teaching-Learning Strategies in brief

1. The learning abilities are incorporated with the help of visualization technology enriched with the advanced text
2. Usage of various software relevant to clinical research will help in active learning
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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DCC201** Title of the Course: Advanced Pharmacology-I

L-T-P: L=64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Understand the underlying pathology of the diseases (Understand level)
CO2	Different categories of drugs acting on different organ systems (Understand level)
CO3	Apply basic pharmacological knowledge in the prevention and treatment of various diseases (Analyze level)
CO4	Describe mechanisms of drug action at organ system/subcellular/ macromolecular levels. (Evaluate level)
CO5	Differentiate between the adverse drug reactions of drugs acting on different systems (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	3	3	3	3	3	1	1	1	3	3	3
CLO2	3	3	3	2	3	3	2	2	2	1	2	3	3
CLO3	3	3	2	3	2	3	3	3	3	3	2	3	3
CLO4	3	3	3	2	3	3	3	1	2	2	1	1	3
CLO5	3	3	2	2	3	3	3	1	2	2	1	1	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Neurotransmission (16 hours)
General aspects and steps involved in neurotransmission. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. Non adrenergic non cholinergic transmission (NANC). Cotransmission
Unit II: Systemic Pharmacology (16 hours)

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems. Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction
UNIT III: Central nervous system Pharmacology (16 hours)
General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.
UNIT IV: Cardiovascular Pharmacology (16 hours)
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: MCR – DCC 202 Title of the Course: Advanced Clinical Research

L-T-P: L=64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Understand the drug discovery process to contribute to the drug development process (Understand level)
CO2	To gain knowledge about molecules characteristics that could successfully treat patients (Understand level)
CO3	Apply knowledge and scientific principles to evaluate pre-clinical data (Analyze level)
CO4	Apply clinical research knowledge to develop Clinical Development Plan (Analyze level)
CO5	Appreciate the current strategies/trends in pharmaceutical product development (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO2	3	1	2	3	2	2	3	3	3	3	3	1	3
CLO3	3	2	1	2	2	3	3	3	3	3	3	1	3
CLO4	3	2	1	3	2	3	1	3	3	3	3	1	3
CLO5	3	2	3	2	2	2	3	3	3	3	3	1	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I – Drug development process and Drug discovery (16 hours)	
1	The drug development process; high throughput screening (HTS), Combinatorial chemistry, Lead optimization, target-centered drug design, Problems in extrapolating data from animals to humans
UNIT-II –Formulation Development (16 hours)	
	Introduction to different formulations, advantages and disadvantages of common formulations, Introduction to manufacturing of drugs and Good

	Manufacturing Practices (GMP), Quality assurance and quality control during manufacturing a drug, Biopharmaceutical classification on drugs
UNIT III – Non Clinical Testing (16 hours)	
	Introduction to toxicology ,Acute, sub-acute and chronic toxicity, Organ specific toxicity, Mutagenicity, teratogenicity and carcinogenicity, Effect on reproductive system , Bioassays, Animal models of certain diseases
UNIT IV – Drug Evaluation and clinical development (16 hours)	
	Phases of developmental clinical trials, Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV, Placebo response, advantages and disadvantages of placebo

Reference Books:

1. Principles and practice of Pharmaceutical Medicine edited by Lionel D. Edwards, Andrew J Fletcher, Anthony W Fox; Wiley; Edition second
2. New Drugs: Discovery and development, edited by Alan A. Rubin;Marcel Dekker
3. The textbook of pharmaceutical medicine by Griffin, J.P. and O'Grady, J. eds.Blackwell

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DCC 203** Title of the Course: **Clinical Research Practicals and Hands -on training**

L-T-P: P=128 Credits: 8
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Estimate different baseline characteristics of the patients enrolled in the clinical trials (Evaluate level)
CO2	Evaluate parameters of heart functions (Evaluate level)
CO3	Apply basic knowledge clinical research in the assessment of volunteers as a trial participant (Analyze level)
CO4	Interpret the biochemical analysis and adverse event reports (Analyze level)
CO5	Understand the advanced analytical techniques (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO1	3	3	2	2	3	3	3	3	3	3	3	3	3
CLO2	3	3	3	2	3	1	1	2	3	1	3	3	3
CLO3	3	2	2	3	3	3	2	2	3	3	3	3	3
CLO4	3	3	3	3	2	2	3	3	2	3	3	3	3
CLO5	3	3	3	2	3	3	3	3	3	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write ‘3’ in the box for ‘High-level’ mapping, 2 for ‘Medium-level’mapping, 1 for ‘Low-level’mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I-Physical Measurements (32 hours)	
1	Measurement of Pulse rate, BP, Temperature Assessment of Height, weight, demography, waist ECG recoding Application of Simple statistical test to the results obtained in above tests
UNIT II –Training at Industry (90 hours)	
	Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrollment of subjects, obtaining informed consent, monitoring of drug administration, adverse events, vital functions, collection and processing of blood samples, SOPs, protocol design, adverse event reporting. Some practical exercise will comprise use of statistical packages in clinical research Basic orientation to common analytical instruments used in clinical research: LC-MS and related instruments Validation and calibration of biomedical instruments Students will be exposed to ongoing clinical research activities viz., o Different Phases of CTs, o Bioavailability (BA) and bioequivalence (BE) studies, o Pharmacokinetics & pharmacodynamics o Monitoring and auditing of CTs, data management o Statistical software used in clinical research and o Drug regulatory activities.

Reference Books:
NA

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DSE 201:** Title of the Course: **Pharmacoepidemiology and Pharmacoeconomics**

L-T-P: L=32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Design and develop epidemiological study (Create level)
CO2	Design and develop Pharmacoeconomics study (Create level)
CO3	Distinguish the type of clinical study (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	1	3	3	2	1	2	3	3	2	3	3	3
CLO2	3	1	3	3	2	1	2	3	3	2	3	3	3
CLO3	3	3	3	3	3	3	3	3	3	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I - Pharmacoepidemiology (16 hours)
Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology
UNIT II - Introduction to Pharmacoeconomics: (16 hours)
Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting. Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

Reference Books:

1. Epidemiology: Basis for Disease Prevention and Health Promotionby David DuncanCollier Macmillan publishers 5th edition, Clinical Epidemiology: The Essentialsby Robert H. Fletcher and Suzanne W. Fletcher; WHO Press;5TH Edition, 3.Methods byBrian MacMahon and Thomas F. Pugh;Lippinkot William and Wilkins;2nd Edition,Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds.
John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health
Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DSE 202** Title of the Course: **Intellectual Property Rights and Patenting**

L-T-P: P= 32 Credits: 2

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Understand the basic concepts of Intellectual property rights and patents (Understand level)
CO2	Create the plagiarism-free documents (Create Level)
CO3	File the patent (Create Level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	1	3	2	3	3	1	3	3	3	3	3	3
CLO2	3	3	3	3	3	3	1	3	3	3	3	3	1
CLO3	1	3	3	3	2	3	1	3	3	3	3	3	1

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I General concepts Intellectual Property Rights & International Institutions (16 hours)	
	Intellectual Property overview and its theory Requirement for Protecting Intellectual Property- a national and international comparison Types of Intellectual Property- Origin and Development- An Overview. World Intellectual Property Organization (WIPO) Role of WIPO and its association with World Trade Organization (WTO) Commercialization of Intellectual Property Rights by Licensing Financial values of Intellectual Property Rights (IPR)
UNIT II Patent Laws Introduction to Copyrights and Trademarks (16 hours)	
	Indian Patent Law The Patents Act, 1970 and its amendments Criteria for Patentability

	Filing Patent Applications and its Granting procedure Patent Infringement International Laws Paris Convention and Patent Cooperation Treaty World Trade Organization- Trade-Related Aspects of Intellectual Property Rights (WTO- TRIPS) agreement, CBD Indian copyright law, types of copyright etc. Types of trademarks, Indian trademark law etc.

Reference Books:

1.Correa, C.M., 2000. Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. Zed books.
2. Vaver, D., 1997. Intellectual property law: Copyright, patents, trade-marks. Irwin Law.
3. Prabu, S.L. and Tnk, S. eds., 2017. Intellectual property rights

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- GEC 201** Title of the Course: **Recent advances in Public Health**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Explain the concept of public health (Evaluate level)
CO2	Summarize the policies of the healthcare system in India (Analyze level)
CO3	Understands the concepts of the health and wellbeing (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO1	3	1	3	3	2	3	2	3	3	3	3	1	3
CLO2	3	2	3	1	3	2	2	3	3	3	3	1	3
CLO3	3	3	3	1	3	3	2	1	3	3	3	2	3

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Detailed Syllabus:

Unit I: Introduction to Public Health (16 hours)	
	Comprehensive Health Care Social Development and Health Dimensions and Determinants of Health Concepts and Indicators of Health and Wellbeing Levels of Prevention Globalisation and Its Impact on Health Roles and Responsibility of State, Community and Private Sector in Health
Unit II: Evolution of Health Policies and Health Services in India (16 hours)	
	Health Committees and Development of Health Services in Independent India Constitutional Provisions, Federal Structure and Social Security National Health Policies (1983, 2002, 2017), Population Policy, Nutrition Policy, Policy on Indian Systems of Medicine and Homeopathy, 2002 Important Health Legislations in India Health Infrastructure in India—Public, Private, and Charitable, Public Private Partnership (PPP) Health financing and Health insurance, Out of Pocket expenditure Civil society and Social Movements in Health

Reference Books:

1. UGC social medicine and community health.
2. Textbook of Preventive and social medicine by K. Park

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- GEC 202** Title of the Course: **Health and Human Rights**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Explain the concepts of health and human right (Evaluate level)
CO2	Explain the policy associated with the heath system of the country (Evaluate level)
CO3	Understands the issues with maternal and child health (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO1	3	3	1	3	3	3	2	2	3	3	3	1	3
CLO2	2	3	3	3	3	2	3	2	3	3	3	3	3
CLO3	2	3	3	3	3	3	3	3	3	3	3	3	3

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Detailed Syllabus:

Unit I: **Health Education and Information Technology in Health (16 hours)**
Concepts, objectives and approaches of health education Methods, modes and barriers of communication Planning, Management and Organization of health education programs E-medicine, Distance education and associated legal issues Role of media in Health Education E Health and m Health
Unit II - **Demography, Family Welfare and RCH (16 hours)**
a. Demography and Family Planning Definition, concepts and indicators related to demography and family planning Demographic cycle Size, composition and distribution of India's population Approaches and methods of contraception Evolution of National Family Welfare Program Social issues related to Family Planning Felt need and unmet need in Family planning Social marketing in family planning Counseling in Family planning Pre-Conception and Pre-Natal Diagnostic Techniques (PC and PNDT) Act-1994 Medical Termination of Pregnancy (MTP) Act 1971 **b. Reproductive and Child Health** Evolution of Maternal/ Reproductive and child Health programs Safe motherhood and essential newborn care with related schemes and programs Gender issues in women's health Major health problems of children in India and related National Health Programs Adolescent health and related schemes and programs Rights of child and related schemes and Programs School Health Programme

Reference Books:

1. UGC social medicine and community health.
2. Textbook of Preventive and social medicine by K. Park

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- SEC01** Title of the Course: **Medical Writing**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Construct protocol, SOP, and ICF for clinical studies (Create level)
CO2	Prepare abstract for clinical and preclinical studies (Create level)
CO3	Prepare clinical study reports as per ICH guidelines (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

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CLO2	3	1	1	2	3	3	2	2	3	2	3	3	3
CLO3	3	1	1	3	3	2	1	2	3	2	3	3	3

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Detailed Syllabus:

Unit I:Introduction to Medical Writing (16 hours)
Basic introduction to medical terminology and fundamentals of medical writing, Literature survey-Use of books and journals and internet, Designing and development of clinical research documents i.e. protocol, Informed consent form (ICF), case record form (CRF), Standard Operating Procedure (SOP) on various functional clinical trial procedures, Research report and paper writing,Plagiarism
Unit II: Medical Writing Tools (16 hours)
Patient narrative preparation, Abstracts & manuscript, Writing of Clinical Study reports, Educational materials for subjects in clinical research, Softwares relevant to medical writing, Periodic Safety Update Report (PSUR),Periodic Benefit Risk Evaluation Report(PBRER), ISCR

Reference Books:

1.Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books; August 2014
2.Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011
3.Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012

Teaching-Learning Strategies in brief

1. The learning abilities are incorporated with the help of visualization technology enriched with the advanced text
2. Usage of various software relevant to clinical research will help in active learning
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4. Incorporation of assessment based on tests in timed google form has elated the active participation of the students
5. Mock case presentation of situations pertaining to clinical research gives an insight of real time activities at clinical research industry
6. Simulation experiments supports the investigation of critical situations without risk

Assessment methods and weightages in brief

The performance of the student in each paper will be evaluated both continuously (Internal Assessment) and at the end of semester (Semester Examination). 25% marks for each theory paper will be allocated for internal assessment and 75% marks will be kept for semester examination at the end of each semester

COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- SEC02** Title of the Course: **Health Communication**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Explain the concepts of health communication (Evaluate level)
CO2	Identifies the current issues associated with health communication (Analyze level)
CO3	Develops and identify healthy communications with patients and caregivers (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	2	2	3	3	3	3	3	1	3	3	3
CLO2	3	3	3	3	3	3	3	2	2	1	3	3	3
CLO3	2	2	3	3	2	3	3	1	1	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I**: Introduction to Health Communication (16 hours)**	
	Defining Health Communication, Communication & healthcare system in India, why is Health Communication Important?, History and Current Issues, Patient-Caregiver Communication, Caregiver Perspective, Patient Perspective, Diversity Among Patients, Social support
Unit II: **Health Communication Approaches and Action areas (16 hours)**	
	Interpersonal Communications, Public Relations, and Public Advocacy, Community Mobilization, Professional Medical Communications, Constituency Relations in Health Communication

Reference Books:

1. Renata Schiavo. HEALTH COMMUNICATION FROM THEORY TO PRACTICE (2nd edition). Published by Jossey-Bass
2. Health Communication in the 21st Century (2nd ed.), by Wright, Sparks & O'Hair. Wiley-Blackwell, 2103. ISBN: 978-0-470-67272-3.
3. Kreps, G.L. (Ed.). (2014). Readings in health communication.

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- SEC03** Title of the Course: **Tropical Medicine**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Understands the disease associated with the tropical region (Understand level)
CO2	Explains the pathophysiology of the disease of the tropical region (Evaluate level)
CO3	Understands the epidemiology of tropical region (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	3	3	3	3	3	3	3	1	3	3	3
CLO2	3	3	3	3	3	3	3	1	3	1	3	3	3
CLO3	3	2	3	2	2	3	3	2	3	1	1	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: History of Tropical Diseases (16 hours)
Natural history of tropical diseases- Leishmaniasis, Elephantiasis, Amoebic dysentery, African trypanosomiasis (sleeping sickness), Hookworm infection, Chagas disease, river blindness. Pathophysiology in various tropical diseases, Common infectious agents in tropics and their properties, Modes of transmission of disease.
UNIT II: Epidemiology of Tropical Diseases (16 hours)
Epidemiology of tropical diseases, Laboratory and radiological investigations in the diagnosis of tropical diseases, Treatment modalities, Preventive aspects, and control measures

Reference Books:

1.Medical Entomology for Students by Mike Service,Manson's Tropical Diseases by Jeremy Farrar et al
2.Atlas of Tropical Medicine and Parasitology by Wallace Peters
3. Oxford Handbook of Tropical Medicine by Robert Davison et al.

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Semester III

Name of the Academic Program MSc Clinical Research

Course Code: **MCR - DCC301** Title of the Course: Advanced Pharmacology-II

L-T-P: L=64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Understand the underlying pathology of the endocrine disorders, infections, gastrointestinal disorders and disorders associated with free radicals (Understand level)
CO2	Different categories of drugs acting on different organ systems (Understand level)
CO3	Apply basic pharmacological knowledge in the prevention and treatment of various diseases (Analyze level)
CO4	Describe mechanisms of drug action at organ system/sub cellular/ macromolecular levels. (Evaluate level)
CO5	Differentiate between the adverse drug reactions of drugs acting on different systems (Analyze level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	2	1	3	3	3	2	1	1	3	1	3
CLO2	3	3	2	1	3	3	3	2	2	1	3	1	3
CLO3	3	2	2	1	3	3	3	1	1	1	3	1	3
CLO4	3	2	2	2	3	2	3	3	1	1	3	2	3
CLO5	3	2	2	1	3	3	3	3	1	1	3	2	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Endocrine Pharmacology (32 hours)
Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones, Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation
Unit II: Chemotherapy (32 hours)
Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs. Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology, Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and Chronic Obstructive Pulmonary Disease (COPD). Immunosuppressants and Immunostimulants
UNIT III: Gastrointestinal (GIT) Pharmacology (32 hours)
Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology -Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer
UNIT IV: Free radicals Pharmacology (32 hours)
Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment:-Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic Basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzun

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: MCR – DCC 302 Title of the Course: Clinical Trial Design

L-T-P: L=64 Credits: 4
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Understand the different trial design for drug discovery (Understand level)
CO2	Explains different phases in clinical trial (Evaluate level)
CO3	Explain the bio-availability and bio-equivalence study (Evaluate level)
CO4	Understands different parameter associated with clinical trial design (Understand level)
CO5	Develop trial design for common diseases (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	2	3	1	3	1	3	3	3	3	3	3	3
CLO2	3	2	3	3	3	2	3	3	3	3	3	3	3
CLO3	3	3	3	3	3	2	3	3	3	2	3	3	3
CLO4	3	2	3	3	2	2	3	3	2	2	3	3	3
CLO5	3	1	2	3	2	3	3	1	2	2	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I: Phases of clinical trial (16 hours)
Phases of clinical trials Designing phase I, II, III, and IV trials: Design types, their characteristics, and parameter to measure, endpoints, inclusion and exclusion criteria Trials for special populations: pediatric, geriatric etc
UNIT II: Introduction to clinical trial design (16 hours)
Methods of randomization, blinding, Screening and recruitment of subjects Placebo Biomarkers
UNIT III: Type of studies (16 hours)

Randomized trial, open label study, double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non-inferiority trials.
UNIT IV: Designing of clinical trials for common diseases (16 hours)
Trial designs of common diseases like cardiovascular, central nervous system, cancer and metabolic disorders BA-BE study designs

Reference Books:

1 Methods for the Economic Evaluation of Health Care Programmes Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg; Oxford University Press 2005

2 Health Economics. Fundamentals and Flow of Founds. Thomas E. Getzen;Wiley;4th Edition

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DCC 303** Title of the Course: **Clinical Research Practicals and Hands-on training**

L-T-P: P=256 Credits: 8
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Prepare clinical trial-related documents like protocols, informed consent documents and case report form (Create Level)
CO2	Apply basic knowledge of drugs and prepare safety reports as per regulatory guidelines (Analyze level)
CO3	Assess and interpret the adverse event reports of various drugs used for the treatment (Analyze level)
CO4	Learn standard operating procedures for various trial-related operations (Analyze level)
CO5	Understand the pharmacokinetics and pharmacodynamics in clinical studies (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	1	2	3	3	3	3	1	3	3	1	3	3	3
CLO2	3	2	1	3	2	1	1	3	3	3	3	1	3
CLO3	3	3	3	3	3	3	2	3	3	1	3	3	3
CLO4	3	3	3	3	3	3	2	1	3	3	3	1	3
CLO5	3	1	1	3	3	3	3	1	3	3	3	1	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT I (56 hours)	
1	• Preparation of problem-based protocol • Preparation of Case Report Form (CRF) and informed consent document (ICD) • Safety Reports • Mock Case report – Causality assessment • Aggregate Safety reports • How to take case history, narrative review
UNIT II: Industrial Training (200 hours)	

	Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrolment of subjects, obtaining informed consent, monitoring of drug administration, adverse events, vital functions, collection and processing of blood samples, SOPs, protocol design, adverse event reporting. Students will also be exposed to ongoing clinical research activities viz., different Phases of CTs, bioavailability (BE) and bioequivalence (BE) studies, pharmacokinetics, pharmacodynamics, monitoring and audit of CTs, data management, drug regulatory activities and statistical software used in clinical research

Reference Books:
NA

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief
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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DSE301:** Title of the Course: **Clinical Trial Operations**

L-T-P: L=32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Explain the step-by-step approach to design and conduct of clinical trials (Evaluate level)
CO2	Apply knowledge to initiate and organise clinical trials (Analyze level)
CO3	Prepare clinical trial report based on data generated in clinical trials and interpret data (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	1	3	3	3	3	3	3	3	3	3	3
CLO2	3	1	2	3	3	3	3	3	3	2	3	3	3
CLO3	3	2	2	2	3	1	3	1	3	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Site initiation (11 hours)
Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection The roles and responsibilities of the following in clinical trial: Sponsor, institution, Clinical Trial Coordinator: Clinical Investigator Documents required at site, Site initiation and conduct activities: Protocol, Case Report Form (CRF), Informed Consent Document (ICD), Investigator brochure, Clinical trial agreement, ethics Committee and regulatory approval, site-initiation visits
Unit IIa: Site conduct (11 hours)
Recruitment, Recruitment, Investigational Product (IP)/Investigational Medicinal Product (IMP)/Pharmacy file receipt and storage, CT site master file, Databases, SOPs

Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections independent data monitoring activities Contingency planning to prepare for unexpected situations.
UNIT IIb: Site close-out activities (10 hours)
Suspending and premature termination of a trial Handling missing data, query and resolution Database lock Site close-out report, Clinical study report, submission to ethics committee and regulatory agency, publication of results

Reference Books:

1. Principles and practice of Clinical Research by John. I Gallin.;Academic Press;3rd Edition
2. Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press; Ist Edition
3. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR – DSE302** Title of the Course: **Pharmacovigilance**

L-T-P: P= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Understand the basic concepts of pharmacovigilance (Understand level)
CO2	Explain risk-benefit ratio associated with drug safety (Evaluate level)
CO3	Reports Adverse drugs reactions to regulatory authority (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	2	3	3	2	3	1	3	3	3	3	3	3
CLO2	3	3	3	2	3	3	1	1	3	3	3	3	3
CLO3	1	3	3	3	3	2	1	3	3	3	3	3	2

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: (16 hours)	
1	• Introduction to Pharmacovigilance • Definition and classification of ADRs • Detection, reporting and causality assessment • Pharmacovigilance in India and global perspective • Pharmacovigilance methods, passive surveillance-spontaneous reports and case series • Active surveillance-drug event monitoring and registries • Basic tools used in pharmacovigilance • Safety studies • Importance of pharmacovigilance
Unit II: (16 hours)	
	• Pharmaceutical preparations (Adverse effects) • Product surveillance and post marketing • Signal detection and follow-up • Communicating safety signals with stakeholders

	• Erice Declaration • Risk management studies • Introduction to translational medicine • Drug monitoring • Pharmacovigilance in drug regulation • Overview of various software used in pharmacovigilance

Reference Books:

1. Textbook of Pharmacoepidemiology, Edited by Brian L. Storm and Stephen K. Kimmel;Wiley Blackwell;5TH Edition
2. Pharmacovigilance by Ronald D. Mann, Elizabeth Andrews; Wiley Blackwell;3RD Edition

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- DSE303** Title of the Course: **Medical Coding**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Explain the concepts of medical coding (Evaluate level)
CO2	Code adverse drug reaction as per the medical dictionaries (Create level)
CO3	Understands the guidelines associated to medical coding (Understand level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	2	3	3	3	1	3	2	3	1	3	3	3
CLO2	2	2	2	3	3	3	3	2	3	1	3	3	2
CLO3	3	2	3	3	1	3	3	3	3	3	3	1	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Terminology in medical coding (16 hours)	
1	• MedDRA- Medical dictionary for regulatory activities. • WHO-DDE-World Health Organization Drug dictionary. • WHO-ART-World Health Organization Adverse reaction terminology
Unit II: ICH guidelines (16 hours)	
	• ICD9-International Classification of Diseases 9 Revision. • ICD10-International Classification of Diseases10 Revision

Reference Books:

1. Guidelines on ICD9 and ICD10

Teaching-Learning Strategies in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR- GEC301** Title of the Course: **Social medicine and community health**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this course, the students should be able to:

CO1	Explain the common health problems of the country (Evaluate level)
CO2	Understands the epidemiology of common health problems (Understand level)
CO3	Explains the national health programs of India. (Evaluate level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	3	3	3	3	3	3	2	2	3	2	3
CLO2	3	3	3	3	3	3	3	3	3	3	3	3	3
CLO3	3	3	2	3	1	2	3	3	3	3	3	3	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write ‘3’ in the box for ‘High-level’ mapping, 2 for ‘Medium-level’ mapping, 1 for ‘Low-level’ mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Social Sciences and Health (16 hours)	
	Definition, Scope, Concepts and Significance of Social, Economic, Cultural and Behavioral factors on Health and Disease Social Theories of Causation of Disease Implications of Social Structure and Socio-economic Status for Health Political and Economic Aspects of Health Health Perceptions and Behaviour Health Economics Qualitative Research Methodology Social Work Approach in Health Care
Unit II -Epidemiology of Common Health Problems In India and National Health Programmes (16 hours)	
	Communicable Diseases—Common, Emerging and Re-emerging diseases, Hospital acquired infections, Antimicrobial resistance Non-Communicable Diseases—Cardio-vascular diseases, Diabetes, Cancers, Rheumatic heart disease, Blindness, Mental Health, Occupational Diseases, Genetic diseases Accidents , Injuries and Disasters All National Health Programs and data sources

Reference Books:

1. UGC social medicine and community health.

Teaching-Learning Strategies in brief

1. The learning abilities are incorporated with the help of visualization technology enriched with the advanced text
2. Usage of various software relevant to clinical research will help in active learning
3. Discussions and presentation by the students utilized during lectures enhances problem-based learning among the students
4. Incorporation of assessment based on tests in timed google form has elated the active participation of the students
5. Mock case presentation of situations pertaining to clinical research gives an insight of real time activities at clinical research industry
6. Simulation experiments supports the investigation of critical situations without risk

Assessment methods and weightages in brief

The performance of the student in each paper will be evaluated both continuously (Internal Assessment) and at the end of semester (Semester Examination). 25% marks for each theory paper will be allocated for internal assessment and 75% marks will be kept for semester examination at the end of each semester

COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Name of the Academic Program MSc Clinical Research

Course Code: **MCR-GEC 302** Title of the Course: **Research Methodology**

L-T-P: L= 32 Credits: 2
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CO1	Explains the various steps involved in the research (Evaluate level)
CO2	Explain the ethical issues pertaining to the research (Evaluate level)
CO3	Develops the communication skill associated with research (Create level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	3	3	2	3	3	3	3	2	3	3	3	3	3
CLO2	3	3	2	3	1	3	1	3	3	3	3	1	3
CLO3	3	2	1	3	2	3	3	3	3	3	3	2	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

Unit I: Research aptitude (16 hours)	
1	Research: Meaning, characteristics and types Identifying a research problem, hypothesis Steps of research Ethical issues in research: Ethics involving use of animal and human subjects, professional ethics, publication ethics
Unit II: Communications Skills for research (16 hours)	
	Development of communication skills in presentation of scientific seminars, eye to eye contact, facing to audience, question & answer sessions etc. Art of scientific writing: Steps to better writing, flow method, organization of material and style, drawing figures, graphs, tables, footnotes, references etc. in a research paper.

Reference Books:

1. Professional communication skills by Praveen S.RBhatia, A.KJain; S.Chand Publishing 2008
2. Communication: The Key to effective Leadership by Judith A Pauley 2009; ASQ quality press
Communicating effectively; Tools for Educational Leaders by Michael B.Gilbert;3rd December 2012

Teaching-Learning Strategies in brief

1. The learning abilities are incorporated with the help of visualization technology enriched with the advanced text
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Assessment methods and weightages in brief

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COURSE DESIGN

CENTER FOR TRANSLATIONAL AND CLINICAL RESEARCH

Semester IV

Name of the Academic Program MSc Clinical Research

Course Code: **MCR-DCC401** Title of the Course: Dissertation

L-T-P: L-320 Credits: 20
(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE LEARNING OUTCOMES (CLOs)

After completing this Course, the students should be able to:

CLO-1	Develop an independent and sustained critical investigation (Create Level)
CLO-2	Evaluate the chosen research topic relevant to clinical research (Analyze level)
CLO-3	Identify relevant theory and concepts, relate these to appropriate methodologies and evidence, apply appropriate techniques and draw appropriate conclusions (Analyze level)
CLO-4	Critical review of appropriate and relevant information sources (Analyze level)
CLO-5	Apply qualitative and/or quantitative evaluation processes to original data (Analyze level)
CLO-6	Apply ethical standards of conduct in the collection and evaluation of data and other resources (Analyze level)
CLO-7	Demonstrate research concepts and contexts clearly and effectively both in writing and orally (Create Level)

Mapping of Course Learning Outcomes (CLOs)with Program Learning Outcomes (PLOs) and Program Specific Outcomes (PSOs)

	PLO 1	PLO 2	PLO 3	PLO 4	PLO 5	PLO 6	PLO 7	PLO 8	PLO 9	PSO 1	PSO 2	PSO 3	PSO 4
CLO1	2	3	2	3	3	2	3	3	3	3	3	3	3
CLO2	3	3	2	3	3	3	3	2	3	2	3	3	3
CLO3	3	3	3	3	2	3	2	3	3	1	3	3	3
CLO4	3	2	2	1	3	3	3	2	3	1	3	2	3
CLO5	1	3	2	3	3	3	3	3	3	1	3	3	3
CLO6	1	3	3	3	3	2	3	3	3	1	3	3	3
CLO7	2	3	3	3	3	3	3	3	3	1	3	2	3

Each Course Learning Outcome (CLOs) may be mapped with one or more Program Learning Outcomes (PLOs). Write '3' in the box for 'High-level' mapping, 2 for 'Medium-level'mapping, 1 for 'Low-level'mapping. Map with PSOs wherever applicable.

Detailed Syllabus:

UNIT 1 (320 Hours)
A project will be given in the course structure in the 4th semester. Under this assignment, a candidate shall be required to write a Dissertation/Drug Profile/Meta-analysis/Pharmacovigilance Report/Protocol Design/Standard Operating Procedure, of a minimum of 5000 words, on a topic allotted to him/her. Topics will be allotted in the 3rd Semester. The evaluation of the dissertation shall be done at the final Examination by the Examiners as part of the Viva-voce examination. Though for project work the topics shall be given in advance, the credits assigned for the project work shall be awarded at the end

of 4th Semester. For project work, the Head of the Centre shall call a meeting of the teachers of the Centre and assign an appropriate number of students to each teacher to act as the supervisor for project work. The student in consultation with the supervisor shall select a topic for the project work and inform the Head to the Centre.

Reference Books:
NA

Teaching-Learning Strategies in brief

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