PROGRAM CURRICULUM
of
School of Pharmaceutical Sciences
(M.Sc. Clinical)
(Program Code:)
[Applicable w.e.f. Academic Year 2025-26]

JIGYASA UNIVERSITY

Formerly
Himgiri Zee University, Dehradun
(Estd. Under Uttaranchal State Act.No.17, 2003.Approved by UGC Under Sec.2(f))
Post Office Selaqui, Chakrata Road, Dehradun, Uttarakhand,248011

Vision of University

We provide the environment to ignite, nurture, and unleash your potential and talent

Mission Statement

1. Progressive educational proficiencies that stimulate holistic development.
2. Enhancing experiential learning through endorsing an inclusive mindset.
3. Advancing research, nurturing innovations, and catalyzing entrepreneurship.
4. Cultivation of leadership qualities with a strong sense of values and ethics.

Vision of School of Pharmaceutical Sciences (SPS)

To become a global leader in pharmacy education, clinical research, and service, committed towards providing a transformative learning experience in a collaborative and diverse environment focused on improving the health and well-being of the communities.

Mission Statements of SPS

- **M1.**To improve the well-being and quality of life of individuals and communities by educating
  students.
- **M2.**To prepare students to become pharmacists and pharmaceutical scientists who will be leaders in the pharmacy profession.
- **M3.** Research in the pharmaceutical & clinical sciences and its translation into health care
- **M3.** Research in the pharmaceutical & clinical sciences and its translation into health care

About the Program

A. Introduction:

The M.Sc. Clinical Research program offers a comprehensive postgraduate curriculum, equipping students with essential skills and knowledge vital for success in the dynamic field of clinical research. Core courses cover diverse subjects including clinical trial design, regulatory compliance, research ethics, and data analysis. Practical training opportunities, such as internships and research projects, allow students to apply theoretical learning in real-world settings. Graduates emerge prepared for a variety of career paths in pharmaceutical companies, biotechnology firms, research institutions, and regulatory agencies. With a focus on experiential learning and industry relevance,

this program ensures that students are well-prepared to contribute to the advancement of healthcare through evidence-based research and innovation.

B. Credit Framework of 2 Year Graduate Degree in Master in Clinical Research

Semesters (2 Semesters = 1Year)		Core Courses		Discipline Specific Elective Courses		Multidisciplinary Courses	Ability Enhancement Courses	Skill Enhancement Courses	Value Added Courses	Capstone Project & Research Project	Total Credits	No. of Courses/ Year
		Major Core Courses (MCC) (4c)	Major Discipline Course (MDC) (4c)	DSE (Major) (3c)	DSE (Minor) (3c)	MLC (3c)	AEC (3c)	SEC (3c)	VAC (2c)	CAP (4c) & REP (12c)		Total Credits/ Year
I	No. of Courses	04				01	01				06	24
	Course Credits	**16**				**04**	**04**				**24**	
II	No. of Courses	04				02		01			07	**25**
	Course Credits	**16**				**08**		**01**			**25**	
III	No. of Courses	03				02	01	01			07	25
	Course Credits	**12**				**08**	**04**	**01**			**25**	
IV	No. of Courses									01	01	**22**
	Course Credits									**22**	**22**	
Course Credits											**96**	**96**

Students, upon exit, shall be awarded the degree of Master of clinical Research (M.sc CR.) with a Major and Minor in the chosen field(s) of study, upon successful completion of 96 credits.

C. National Higher Education Qualifications Framework (NHEQF) levels:

NHEQF Level	NHEQF Level	NHEQF Level	NHEQF Level	NHEQF Level
Level 7	**Master's Degree** *(2 years)*	Bachelor's Degree	~ 80 Credits	Core disciplinary knowledge and cognitive skills
Level 8	M.Phil. / PG Diploma / PG Certificate (or equivalent as per framework)	Master's Degree	~40–60 Credits	Specialized and advanced knowledge, research aptitude, and critical thinking skills
Level 9	Doctoral Coursework / Pre-PhD Stage (as per framework)	Master's Degree / Level 8	As prescribed	High-level theoretical and practical knowledge, advanced research and analytical skills
Level 10	Doctoral Degree (Ph.D.)	Master's Degree / Level 9	As prescribed	Creation of new knowledge through original research and contribution to the

				discipline

D. Academic Bank of Credits (ABC):

In alignment with the National Education Policy (NEP) 2020, the Academic Bank of Credits (ABC) facilitates a flexible curriculum framework and promotes interdisciplinary/multidisciplinary academic mobility among students across various Higher Educational Institutions (HEIs) through an appropriate credit transfer system. Accordingly, the School of Business Studies, under Jigyasa University, Dehradun, has developed a comprehensive four-year undergraduate program.

As a prerequisite, students/learners are required to register on the Academic Bank of Credits (ABC) portal. The credits earned during the study will be digitally stored in the ABC account. Learners must complete their program as per the guidelines of the UGC's ABC policy. Please note that the validity of earned credits is limited to seven years (or as per the latest advisory from the competent authority). Additionally, each credit earned may only be used once and cannot be reused for multiple programs or purposes.

E. Curriculum Framework:

The M.Sc. Clinical curriculum framework is designed in accordance with the guidelines of the University and emphasizes a comprehensive approach to undergraduate clinical education. The courses are broadly classified as follows: : Major Core Courses (MCC), Major Discipline Courses (MDC), Discipline Specific Elective Courses- Major& Minor(DSE), Multidisciplinary Courses (MDC), Skill Enhancement Courses (SEC), Ability Enhancement Courses (AEC), Value-Added Courses (VAC), Capstone Projects (CAP), and Research Projects (REP)

This structured framework ensures that students acquire in-depth theoretical knowledge, practical skills, and research competencies essential for professional clinical practice, healthcare industry readiness, and evidence-based pharmaceutical care. It also promotes critical thinking, multidisciplinary exposure, and lifelong learning, preparing graduates to meet the evolving challenges of the healthcare and clinical research sectors.

I. Major Core Courses (MCC):

Major Courses (MCC) provide advanced knowledge and specialized skills in clinical research, healthcare, and biomedical sciences. Key areas include clinical trial design, pharmacovigilance, regulatory affairs, biostatistics, and healthcare management.

Core MCC courses, such as Advanced Clinical Trial Design, Pharmacovigilance and Drug Safety, Regulatory Affairs, Healthcare Systems, and Clinical Data Analytics, equip students to design studies, manage clinical data, ensure patient safety, and comply with global guidelines.

MCCs develop analytical, practical, and professional competencies essential for careers in clinical operations, research, and healthcare management.

II. Major Discipline Courses (MDC)

Major Discipline Courses (MDC) provide students with a strong foundation in clinical research, biomedical sciences, and healthcare management, integrating theoretical knowledge with practical

and professional skills. These courses are designed to enhance analytical thinking, problem-solving abilities, ethical awareness, and research competence, all of which are essential for careers in the clinical and healthcare sectors.

The curriculum covers key areas such as Clinical Research Methodology, Pharmacology, Medical Therapeutics, Pharmacovigilance, Biostatistics, Bioethics, and Regulatory Affairs, offering students comprehensive knowledge of clinical trial operations, drug development, and patient safety.

Advanced courses—including Clinical Data Management, Molecular Diagnostics, Hospital Management and Law, Research Methodology, and Project Work (Minor and Major/Internship)—prepare students for professional roles in clinical operations, data analysis, regulatory compliance, and applied health research.

III. Discipline Specific Elective Courses – Major & Minor (DSE)

Aligned with NEP 2020, the M.Sc. Clinical Research program offers specializations that integrate theoretical knowledge, practical exposure, and hands-on training, enabling students to acquire advanced domain-specific competencies. Introduced in the later semesters, these modules build on a strong foundation in core clinical sciences and prepare students for specialized research and professional roles in the healthcare and clinical research sectors.

IV. Multidisciplinary Courses (MLC)

Multidisciplinary Courses (MLC) in the M.Sc. Clinical Research program are designed to integrate knowledge from diverse scientific and healthcare disciplines, providing students with a comprehensive understanding of clinical research and healthcare systems. These courses go beyond core clinical subjects to demonstrate how interdisciplinary knowledge supports problem-solving, innovation, and evidence-based decision-making in patient care and research. They also emphasize adaptability, critical thinking, and ethical responsibility as essential competencies for successful professionals in clinical research and healthcare.

V. Skill Enhancement Courses (SEC)

Skill Enhancement Courses (SECs) in the M.Sc. Clinical Research program are designed to equip students with practical, professional, and industry-relevant competencies beyond the core curriculum. These courses develop technical, analytical, and applied skills, emphasizing hands-on, job-oriented abilities essential for advanced clinical research and healthcare practice.

The curriculum includes the following key courses**:**

1. Clinical Laboratory Skills – introduces essential laboratory techniques, diagnostic procedures, and clinical assessment methods.
2. Analytical Methods in Clinical Research – focuses on modern techniques for sample analysis, data interpretation, and result validation.
3. Patient Care and Management Skills – provides practical knowledge for patient monitoring, therapeutic evaluation, and clinical decision-making.
4. Quality Assurance and Regulatory Compliance – offers hands-on experience in maintaining research and healthcare standards while adhering to regulatory guidelines.
5. Digital Tools in Clinical Research – trains students to effectively use digital technologies, data management systems, and software applications relevant to modern clinical research and healthcare environments.

VI. Ability Enhancement Courses (AEC)

While generic professional skills such as communication, ethics, and regulatory awareness are often integrated across the curriculum, this category formalizes them through dedicated courses in professional communication, ethical clinical practice, data analysis, and scientific reasoning. These courses enhance students' professional competence, critical thinking, and ethical decision-making, preparing them for responsible and effective roles in clinical research and healthcare system.

VII. Value-Added Courses (VAC)

This category is not part of the university marksheet, but is offered as a supplementary certificate. Students receive a certificate upon successful completion of the module, which highlights their skill development and readiness for industry, research, and professional practice. It is retained for supplementary modules such as Entrepreneurship, Intellectual Property in Clinical Science, and Digital Tools etc. in Clinical Sciences.

VIII. Capstone Project (CAP):

The Capstone Project (CAP) in the M.Sc. Clinical Research program provides students with an opportunity to integrate and apply the knowledge and skills acquired throughout the course to real-world clinical and healthcare research challenges. It serves as the culmination of learning, emphasizing critical thinking, problem-solving, research aptitude, and professional competence.

Students undertake projects in areas such as clinical trial data analysis, hospital-based research, patient care evaluation, biomedical investigations, epidemiology, or public health studies. Under faculty guidance, they plan, execute, and present a comprehensive project demonstrating their ability to collect and analyze data, interpret findings, and propose practical, evidence-based solutions.

The Capstone Project fosters independent learning, innovation, and interdisciplinary application, bridging theoretical knowledge with practical implementation. Successful completion enhances students' research and professional competencies, preparing them for advanced studies, clinical research careers, and roles in healthcare and biomedical industries.

IX. Research Project (REP):

Although general project work is a standard component of postgraduate programmes, the term "research project" is retained separately in the M.Sc. Clinical Research curriculum to emphasise students' engagement in research-oriented activities. This category highlights deeper involvement in laboratory, clinical, or community-based research that goes beyond routine project assignments. It allows students to develop stronger competencies in scientific inquiry, research design, data interpretation, ethical practices, and evidence-based problem-solving, thereby strengthening their preparedness for professional roles and higher studies in clinical and biomedical research.

Program Matrix

Matrix Course Category Name	Course Category Code	Number of Courses	Credits	Total Course Credits
Core Course	CORE	11	4	44
Skill Enhancement Courses	SEC	2	1	2
Multidisciplinary Courses	MLC	5	4	20
Ability Enhancement Courses	AEC	2	4	8
Capstone Project	CAP	1	22	22
TOTAL		**21**		**96**

Types of Courses

Category Name	Number of Courses	Total Number of Course
SEC	Soft Skills	03
AEC	Social Engineering/ MOOCs	06

Whereas : NC – Non Credit, SEC – Skill enhancement Course, AEC – Ability Enhancement Course, MLC – Multidisciplinary Courses

F. Graduate Attributes (GA):

The Graduate Attributes (GAs) underpinning the M.Sc. Clinical Research programs have been adopted in alignment with the National Education Policy (NEP) 2020, University Grants Commission (UGC) guidelines, and the National Higher Education Qualifications Framework (NHEQF). These attributes serve as the foundational principles for defining the Program Educational Objectives (PEOs) and Program Outcomes (POs) outlined below. The curriculum is thus designed to ensure students develop the competencies, values, and capabilities envisioned for undergraduate business education in India.

G. Program Educational Objectives (PEOs)- **(M.Sc. Clinical Research)**

PEO 1: Students will comprehend the basic principles and regulations governing clinical research, including ethical considerations and regulatory frameworks.
PEO 2: Students will critically analyze various perspectives and methodologies used in clinical evaluation studies and design data management systems and trial protocols that optimize data quality, security, and ethical compliance.
PEO 3: Synthesize pharmacological knowledge and drug mechanisms of action to understand their implications in clinical research.
PEO 4: Generate novel research protocols that address unmet clinical needs and contribute to advancements in medical science and healthcare delivery simultaneously evaluate advanced techniques in clinical data management and trial management for their effectiveness and ethical compliance.
PEO 5: Showcase sophisticated critical thinking abilities essential for improving prospects for employment or progression within the clinical research sector.

H. Program Outcomes (POs) - (M.Sc. Clinical Research)

PO	Program Outcome
PO1	Demonstrate understanding of ethical principles and regulatory frameworks in clinical research.
PO2	Gain efficiency to manage Quantitative tools & techniques, Clinical Data Management, Bio-, Pharmaco-, Medico-Informatics, Drug designing, etc.
PO3	Evaluate perspectives and methodologies used in clinical evaluation studies
PO4	Analyze regulatory standards to ensure compliance and prioritize patient safety in clinical trials, by assessing the implications of various regulations on trial protocols and procedures, identifying potential areas of risk, and developing strategies to mitigate these risks while maintaining ethical integrity.
PO5	Develop innovative applications of pharmacological knowledge by synthesizing intricate understanding of drug mechanisms of action.
PO6	Apply advanced techniques in clinical data management for effective trial execution.
PO7	Evaluate the efficacy and safety of pharmaceuticals through rigorous pharmacovigilance practices
PO8	Design and conduct clinical trials ethically and within regulatory guidelines
PO9	Analyze and interpret clinical research findings to inform evidence-based practice
PO10	Efficiently communicate with healthcare professionals and regulatory bodies to cultivate culturally inclusive strategies for securing biopharmaceutical product approvals, both domestically and globally.

Mapping of PEOs & POs in M.sc. CR Articulation Matrix

PO→ PEO ↓	PO1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10
PEO1	3			3				2		1
PEO2	2	3	3	3		3		2	2	3
PEO3					3		2	1	1	
PEO4	2	2	2	3		3	2	3	2	2
PEO5		1	2	2	2	1		1	3	3

Note: *In alignment with Outcome-Based Education (OBE) principles, the mapping of Program Educational Objectives (PEOs) to Program Outcomes (POs) is presented using a* ***quantitative scale (1–3)****, where:*

- ***1*** *indicates a low level of contribution*
- ***2*** *indicates a moderate level of contribution*
- ***3*** *indicates a high level of contribution*

This mapping ensures that each PEO is ***progressively achieved through the attainment of relevant POs****, thereby providing a structured and measurable approach to evaluating the effectiveness of the program in delivering its long-term educational goal.*

J. Pedagogy, Andragogy, and Unique practices adopted:

Pedagogy refers to the art and science of teaching, particularly within academic and professional disciplines. In the M.Sc. Clinical Research programme, the institute follows a comprehensive and learner-centered teaching approach designed to build strong theoretical foundations, practical competence, and research capability.

Alongside structured classroom lectures, students engage in a wide range of experiential and interactive learning methods, including:

- Laboratory practicals and simulations – to develop hands-on skills in clinical laboratory techniques, biomedical testing, sample handling, and data recording**.**
- Case studies, protocol analysis, and problem-solving exercises – to strengthen clinical reasoning, understanding of study designs, ethical decision-making, and application of regulatory guidelines.
- Clinical site visits, hospital exposure, and interactions with research units – to familiarize students with real-world clinical workflows, trial documentation, patient management processes, and Good Clinical Practice (GCP) environments.
- Group discussions, journal clubs, and seminar presentations – to enhance scientific communication, teamwork, critical appraisal of literature, and evidence-based thinking.
- Project-based learning**,** including Capstone Projects and Research Projects**,** to integrate multidisciplinary knowledge, develop research aptitude, and encourage independent investigation in clinical, biomedical, or community-based contexts.

These pedagogical strategies ensure that students gain holistic knowledge of clinical research operations, regulatory frameworks, ethics, trial management, and scientific methodology. By combining lectures, practical sessions, interactive learning, and research engagement, the M.Sc. Clinical Research pedagogy prepares learners for professional roles in clinical trials, pharmacovigilance, medical writing, regulatory affairs, and biomedical research, while also equipping them for advanced studies in the health sciences.

1. Orientation and Bridge Program:

At the commencement of the M.Sc. Clinical Research programme, the School will organize a comprehensive Orientation Program to welcome and guide newly enrolled students. The program aims to familiarize students with academic expectations, institutional values, professional responsibilities, and available support systems, thereby laying a strong foundation for their journey in clinical research and health sciences education.

The Orientation Program plays a crucial role in easing students into university and professional life. It introduces students to the campus environment, faculty members, academic policies, laboratories,

research facilities, and clinical or hospital-linked units. Spanning approximately one week, the program fosters interaction among peers, faculty, and support staff, creating a sense of belonging and community. It also ensures that students understand institutional rules, academic expectations, and available learning resources, enabling a smooth and confident transition into the M.Sc. Clinical Research programme.

Aligned with the objectives of modern higher education and the competencies required in clinical research, the Orientation Program is structured to provide holistic development, academic readiness, and professional growth. The key components include:

- Introduction to College and Professional Life**:** Supporting students in adapting to academic, laboratory, and clinical environments related to research and healthcare.
- Integration with University Culture: Helping students understand the social, ethical, and academic values that guide institutional practices.
- Faculty and Peer Interaction: Encouraging meaningful connections between students, faculty, mentors, and programme coordinators to strengthen engagement and support.
- Linkages with Society and Healthcare Environment**:** Highlighting the role of clinical research in public health, patient safety, community wellbeing, and ethical medical practices.
- Philosophy of Clinical Research Education & Pedagogy**:** Introducing students to the goals, values, and evidence-based teaching methodologies integral to clinical and biomedical education.
- Academic Foundation and Bridge Courses**:** Addressing gaps in core subjects such as biology, chemistry, mathematics, medical terminology, and computer literacy to ensure academic preparedness.
- Personality Development and Professional Skills**:** Developing communication, leadership, teamwork, ethics, and interpersonal skills essential for clinical and research environments.
- Information Technology and Digital Skills**:** Enhancing digital literacy in areas such as data entry, electronic health records, clinical documentation, research databases, and basic biostatistical tools.

This Orientation Program ensures that students begin the M.Sc. Clinical Research programme with confidence, clarity, and readiness to meet the academic, research, and professional expectations of their chosen field.

2. Experiential and Holistic Learning Approach:

To foster experiential learning beyond conventional classroom instruction, the M.Sc. Clinical Research programme integrates a variety of participatory and applied pedagogical approaches. These methodologies are designed to reinforce theoretical knowledge with practical application, enhance critical thinking, and develop professional competencies essential for clinical research and healthcare environments.

Students are encouraged to actively participate in School Clubs and Professional Development Forums, including:

- **VIBGYOR Club** – promoting creativity, interdisciplinary learning, and holistic personal development.
- **Young Leaders' Club** – enhancing leadership, teamwork, communication, and organizational skills.

The programme employs a wide range of interactive and applied teaching–learning methods, including:

- **Case-based Discussions:** Applying theoretical concepts to real-world clinical, biomedical, and research scenarios.
- **Role-plays, Group Assignments, and Presentations:** Developing teamwork, communication, and problem-solving skills essential for professional research and healthcare practice.
- **Video-assisted Learning Sessions:** Facilitating visual understanding of complex laboratory techniques, clinical procedures, and study protocols.
- **Field Assignments, Live Research Projects, and Hospital/Industry Visits:** Providing hands-on exposure to clinical trials, research laboratories, hospitals, and community health settings.
- **Expert-led Interactive Sessions:** Enabling knowledge transfer from experienced researchers, clinicians, and healthcare professionals.
- **Co-curricular and Student Development Initiatives:** Encouraging holistic growth through participation in seminars, workshops, competitions, and community outreach programs.
- **Mentorship Programs:** Offering guidance on academic planning, career development, and professional skills.
- **Workshops and Seminars:** Strengthening practical competencies, research aptitude, and awareness of current trends in clinical research and biomedical sciences.

These experiential and participatory pedagogies ensure that M.Sc. Clinical Research students gain not only strong conceptual knowledge but also the practical skills, ethical understanding, and professional competencies required to excel in clinical research, healthcare, and biomedical research domains. By integrating interactive learning, real-world exposure, and mentorship, the programme prepares students to meet the demands of modern research and healthcare professions.

3. Library and E – Learning Access:

Course faculty actively encourage M.Sc. Clinical Research students to make regular and purposeful use of the University Library, guiding them to effectively utilize its extensive collection of books, journals, reference materials, and digital resources. These resources support academic learning, subject-specific research, laboratory work, and the overall development of knowledge in clinical research, biomedical sciences, and healthcare practices.

In addition, students have access to a wide range of e-learning resources through individual logins on the University's ERP and digital learning platforms. This facilitates continuous learning beyond classroom instruction, enabling students to engage in self-directed study, online research, simulation exercises, data analysis, and virtual laboratory or clinical trial learning experiences.

L. Program Structure

M.Sc. Clinical Research

S. No.	Course Code	Course Name	Category	Numbers of Hours/Week			C
			Core / Elective / Others	L	T	P	
SEMESTER I							
1	MCR 101	Clinical Research Overview	Major Core Course	3	1	-	4
2	MCR 103	Regulation & Ethics in Clinical Research	Major Core Course	3	1	-	4
3	MCR 104	Statistics for Management	Major Core Course	3	1	-	4
4	MCR 105	Perspective in Clinical Evaluation	Major Core Course	3	1	-	4
5	MCR 106	Pharma Regulatory Affairs	AEC	3	1	-	4
6	MCR E108	Site Management Organization	MLC	3	1	-	4
7	SSE 001	Soft Skill Enhancement-I	SEC	-	-	-	NC
8	SE 001	Social Engineering/Yoga/Sports/Extra Curricular activity	AEC	-	-	-	NC
9	MO 001	MOOCs/Foreign Language	AEC	-	-	-	NC
Total				**18**	**6**	**0**	**24**
SEMESTER II							
1	MCR 201	Preclinical Evaluation of Drugs	Major Core Course	3	1	-	4
2	MCR 202	Molecular Mechanism of Drug Action	Major Core Course	3	1	-	4
3	MCR 203	Pharmacovigilance -I	Major Core Course	3	1	-	4
4	MCR 204	Pharmacology –I	Major Core Course	3	1	-	4
5	MCR E205	Designing in Clinical Trial	MLC	3	1	-	4
6	MCR E207	GMP & GLP	MLC	3	1	-	4
7	SSE 002	Soft skill Enhancement –II	SEC	-	-	-	NC
8	PTT 001	Presentation	SEC	-	-	2	1
9	SE 002	Social Engineering/Yoga/Sports/Extra	AEC	-	-	-	NC

		Curricular activity					
10	MO 002	MOOCs/Foreign Language	AEC	-	-	-	NC
Total				**18**	**6**	**0**	**25**
Cumulative Total				**36**	**12**	**2**	**49**
SEMESTER III							
1	MCR 301	Pharmacovigilance -II	Major Core Course	3	1	-	4
2	MCR 302	Pharmacology -II	Major Core Course	3	1	-	4
3	MCR 303	Advance Clinical Data Management	Major Core Course	3	1	-	4
4	MCR 304	Clinical Trail Management	AEC	3	1	-	4
5	MCR E305	Research Methodology	MLC	3	1	-	4
6	MCR E306	Advanced Medical Writing	MLC	3	1	-	4
	PTT 002	Presentation	SEC	-	-	2	1
7	SSE 003	Soft Skills enhancement -III	SEC	-	-	-	NC
8	SE 003	Social Engineering/Yoga/Sports/Extra Curricular activity	AEC	-	-	-	NC
9	MO 003	MOOCs/Foreign Language/Experience learning	AEC	-	-	-	NC
Total				**18**	**6**	**2**	**25**
Cumulative Total				**54**	**18**	**4**	**74**
SEMESTER IV							
1	MCR 401	INTERNSHIP or Project work or Dissertation	CAP	-	-	44	22
Total					**0**	**44**	**22**
Grand Total				**54**	**18**	**48**	**96**

L – Lecture T- Tutorial P- Practical C-Credits

1L = 1Hr 1T= 1 Hr 1P=1 Hr 1C = 1 Hr of Theory Paper per week

= 2 Hrs of Practical/Tutorial per week

NC – Non Credit

Major Core Course (MCC)				
S.No.	Course Name	Category	Code	Semester
1	Clinical Research Overview	MCC	MCR101	I
2	Regulation & Ethics in Clinical Research	MCC	MCR103	I
3	Statistics for Management	MCC	MCR104	I
4	Perspective in Clinical Evaluation	MCC	MCR105	I
5	Preclinical Evaluation of Drugs	MCC	MCR201	II
6	Molecular Mechanism of Drug Action	MCC	MCR202	II
7	Pharmacovigilance – I	MCC	MCR203	II
8	Pharmacology – I	MCC	MCR204	II
9	Pharmacovigilance – II	MCC	MCR301	III
10	Pharmacology – II	MCC	MCR302	III
11	Advance Clinical Data Management	MCC	MCR303	III

Ability Enhancement Course (AEC)				
S.No.	Course Name	Category	Code	Semester
1	Pharma Regulatory Affairs	AEC	MCR106	I
2	Clinical Trial Management	AEC	MCR304	III

Major Discipline Course (MDC)				
S.No.	**Course Name**	**Category**	**Code**	**Semester**
1	Site Management Organization	MDC	MCR E108	I
2	Designing in Clinical Trial	MDC	MCR E205	II
3	GMP & GLP	MDC	MCR E207	II
4	Research Methodology	MDC	MCRE305	III
5	Advanced Medical Writing	MDC	MCRE306	III

Skill Enhancement Courses (SEC)				
S.No.	**Course Name**	**Category**	**Code**	**Semester**
1	Soft Skill Enhancement – I	SEC	SSE001	I

2	Soft Skill Enhancement – II	SEC	SSE002	II
3	Soft Skill Enhancement – III	SEC	SSE003	III
4	Presentation	SEC	PTT001	II
5	Presentation	SEC	PTT002	III

Additional / Ability Enhancement Courses (AEC)				
S.No.	**Course Name**	**Category**	**Code**	**Semester**
1	Social Engineering / Yoga / Sports / Extra Curricular	AEC	SE001	I
2	MOOCs / Foreign Language	AEC	MO001	I
3	Social Engineering / Yoga / Sports / Extra Curricular	AEC	SE002	II
4	MOOCs / Foreign Language	AEC	MO002	II
5	Social Engineering / Yoga / Sports / Extra Curricular	AEC	SE003	III
6	MOOCs / Foreign Language / Experience Learning	AEC	MO003	III

Capstone Project (CAP)				
S.No.	**Course Name**	**Category**	**Code**	**Semester**
1	INTERNSHIP or Project work or Dissertation	CAP	MCR401	**IV**

SEMESTER – I

Program	Master in Clinical Research	Semester-I			
Course Name	Clinical Research Overview	L	T	P	C
Course Code	MCR 101	3	1	0	4

Course Objectives:
This course ensures that the students understand how:

1	Understand basic concepts, types, and phases of Clinical Research.
2	Explain ethical principles, historical events, and GCP guidelines.
3	Describe clinical pharmacology, BA-BE, and drug development process.
4	Understand clinical trial conduct, safety monitoring, and quality systems.
5	Analyze the scope, growth, challenges, and **career opportunities in clinical research**, including the role of AI and Big Data in modern clinical research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the concepts, types, phases, and terminology of Clinical Research.	L2
CO2	Describe the historical evolution and ethical principles (IEC/IRB, ICH-GCP, Nuremberg Code, etc.) in Clinical Research.	L2
CO3	Apply principles of Clinical Pharmacology, Bioavailability, Bioequivalence, and Drug Development in clinical research settings.	L3
CO4	Analyze clinical trial conduct, safety reporting (AE/SAE), pharmacovigilance, QA/QC, and monitoring systems.	L4
CO5	Evaluate modern trends, AI applications, and career opportunities in Clinical Research.	L5

Unit No	Content	Contact Hrs

UNIT I	• Introduction to Clinical Research, Definition of Clinical research, Terminologies & definitions used in Clinical Research, Difference between Clinical Researchand Clinical practice, • Types of Clinical research and Phases of Clinical Research, Role players in the Clinical Research • ,The stand of Clinical Research in Scientific Arena, Basics of Bioavailability, Bioequivalence Studies, Clinical Research Methodology ,Career Prospect in Clinical Research.	**15**
UNIT II	• The Historical prospective of Clinical Research, • A Brief History of Clinical Research, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont Report, Nuremberg Code, Declaration of Helsinki Principles, • Institutional Ethics Committees (IEC)/IRBs – composition and role, Good Clinical Practice (GCP) guidelines – ICH-GCP	**12**
UNIT III	• Introduction to Clinical Pharmacology Definitions: • DrugPharmacology,Pharmacokinetics,Pharmacodynamics,Therapeutics,Toxicology,Chemotherapy,Pharmacoepidemiology and Pharmacoeconomics. • Bioavailability & Bioequivalence (Definitions, Types of Factors affecting in Bioavailability, Significance of BA-BE studies in Clinical Trial. Pharmacokinetics Pharmacodynamics.	**10**
UNIT IV	• Drug Development process Drug discovery, Adverse Events (AE) and Serious Adverse Events (SAE),Pharmacovigilance and signal detection, Risk-based monitoring, Data Safety Monitoring Boards (DSMBs), Clinical trial audits and inspections, • Role of QA and QC in clinical research	**10**
UNIT V	• Electronic data capture (EDC) and clinical trial management systems (CTMS), Real-world evidence and decentralized clinical trials • Role of Artificial Intelligence and Big Data in clinical research, Clinical research in India – growth and challenges, Career roles: Clinical Research Associate (CRA), Clinical Data Manager, Medical	**10**

Suggestive Readings:

"Textbook of Clinical Trials"
1. Editor: David Machin, Simon Day, Sylvan Green
2. "A Beginner's Guide to Clinical Trials" Author: Bethann Siviter

Reference books:

1.Principles and Practice of Clinical Research"
2.Authors: John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson "Clinical Trials: A Methodologic Perspective" Author: Steven Piantadosi

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO–PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1	3	2	1	1	1	1	1	2	1	
CO2	2	2	1	1	1	2	1	3	2	
CO3	3	2	2	2	1	1	1	2	1	2
CO4	2	3	3	2	2	2	1	3	2	
CO5	3	2	2	1	3	2	2	2	3	1

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester -I			
Course Name	Regulation and Ethics in Clinical Research	L	T	P	C
Course Code	MCR 102	3	1	0	4

Course Objectives

:

This course ensures that the students understand how:

1	Understand the ethical foundations and principles governing clinical research involving human subjects
2	Explain the structure, functions, and legal authority of IRB/IEC and global ethical review committees
3	Describe ICH-GCP guidelines, Indian GCP (Schedule Y, ICMR), and regulatory requirements
4	Understand the informed consent process and ethical submission & approval procedures

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain ethical principles in clinical research including the Belmont Report, Declaration of Helsinki, and protection of human subjects.	L2
CO2	Describe the structure, duties, membership, and regulatory authority of IRB/IEC and their role in reviewing clinical drug trials.	L2
CO3	Apply ICH-GCP principles, Indian GCP (Schedule Y, ICMR guidelines), and prepare essential documents	L3

	including protocol, Investigator's Brochure, and informed consent documents.	
CO4	Analyze responsibilities of sponsors, investigators, monitors, and regulators in clinical trial conduct and regulatory compliance.	L5

Syllabus

Unit No	Content	Contact Hrs
UNIT I	Explain ethical principles in clinical research including the Belmont Report, Declaration of Helsinki, and protection of human subjects.	**15**
UNIT II	Guidelines in Clinical Research ICH and Regulations, ICH-GCP GUIDELINES ,The principles of ICH GCP , Institutional Review Board/Independent Ethics Committee (IRB/IEC), Investigator & Sponsor, Clinical trial protocol and protocol amendment (s), Investigator's brochure, Essential documents for the conduct of a Clinical trial ,icmr – guidelines on biomedical research on human subjects	**15**
UNIT III	ICH-GCP: Objectives, principles, and structure, Indian GCP Guidelines (Schedule Y, ICMR Guidelines),Protocol design and regulatory submissions Responsibilities of sponsors, investigators, monitors, and regulators, Informed Consent Process (ICP): Elements, documentation, language, and re-consenting	**12**
UNIT IV	Clinical Research Regulatory submission and Approval process Global + Indian FDA- IND, NDA and ANDA Submission Procedure, DCGI Submission Procedure Indian, Regulatory System: DCGI, Other Regulatory Authorities: EMEA, EU, MHRA, PhRMA etc.	12

Book Text :

1. Ethical guidelines for Biomedical Research on Human Subject, ICRI
2. FDA: Protection of Human Subject, ICRI
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. Clinical Trials: ensuring Patient Safety and Integrity, ICRI

Reference

1. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1	3	2	1	2	1	1	1	2	2	
CO2	3	3	1	2	1	2	1	2	1	1
CO3	3	3	2	1	2	2	1	2	1	
CO4	3	2.	2	1	2	2	1	2	1	
CO5	2	2	1	3	2	2	1	1	1	1

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-I			
Course Name	Statistics For Management	L	T	P	C
Course Code	MCR 104	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	**Analyze** the fundamental concepts and rules of probability and apply them to solve real-life problems involving uncertainty.
2	**Examine** probability distributions and identify appropriate models (Binomial, Poisson, Uniform, Normal) for different datasets.
3	**Analyze** sampling distributions and estimation techniques for large and small samples in research contexts.
4	**Differentiate and evaluate** appropriate statistical tests (parametric and non-parametric) for hypothesis testing.
5	Apply statistical tools for forecasting and decision-making in healthcare, clinical research, and management fields.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Analyze probability concepts including conditional probability, independence of events, Bayes' theorem, and random variables to solve applied statistical problems.	L1
CO2	Examine and compare different probability distributions (Binomial, Poisson, Uniform, Normal) and interpret sampling distributions using the Central Limit Theorem.	L4
CO3	Analyze large and small sample data to compute point and interval estimates and determine appropriate sample sizes for population parameters.	L3
CO4	Differentiate and apply appropriate hypothesis testing procedures (z-test, t-test, F-test, Chi-square test, and non-parametric tests) for analyzing research data.	L2
CO5	Explain the concepts of correlation and regression analysis.	L3

Syllabus:

Unit No	Content	ContactHrs
UNIT 1	• Probability Basic definitions and rules for probability, conditional probabilityIndependent of events, • Baye's Theorem, random variables, Probability distributions: Binomial, Poisson, Uniform and Normal Distributions.	**10**

UNIT II	• Sampling distribution and Estimation ,Introduction to sampling distributions, sampling techniques, • sampling distribution of mean and proportion, application of central limit theorem. • Estimation: Point and Interval estimates for population parameters of large sample and small samples, determining the sample size.	**12**
UNIT III	• Testing of Hypothesis Hypothesis testing: one sample and two samples tests for means and proportions of large samples (z-test), • one sample and two sample tests for means of small samples (t-test), F-test for two sample standard deviations.	**12**
UNIT IV	• Non- Parametric Methods Sign test for paired data. Rank sum test: Mann –Whitney U test and Kruskal Wallis test. • One sample run test, Rank correlation. Chi-square tests for independence of attributes and goodness of fit.	**10**
UNIT V	• Correlation, Regression and Time Series Analysis Correlation analysis, estimation of regression line. • Time series analysis Variations in time series, trend analysis, cyclical variations, seasonal variations and irregular variations.	**10**

Suggested Readings:

1."Business Statistics: A First Course", Levine D.M., Krehbiel T.C. and Berenso Pearson Education Asia, 2nd edition, New Delhi, 5th Edition, 2009

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1	3	1	1	1	2	1	1	2	1	2
CO2	2	2	2	1	1	2	2	3	1	
CO3	2	1	1	3	1	1	1	2	2	2
CO4	2	2.	3	1	1	2	1	3	1	
CO5	3	1	2	1	2	1	2	3	2	

_1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	**Master in Clinical Research**	**Semester-I**			
Course Name	**Perspective in Clinical Evaluation**	**L**	**T**	**P**	**C**
Course Code	**MCR 105**	**3**	**1**	**0**	**4**

Course Objectives:

This course ensures that the students understand how:

1	To understand the scope and regulatory framework of clinical evaluation.
2	To learn clinical evaluation processes and ethical requirements.
3	To understand planning, appraisal, and risk–benefit assessment in clinical studies.
4	To understand preclinical studies and extrapolation to human trials.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain scope and regulatory aspects of clinical evaluation.	L2
CO2	Apply clinical processes and ethical requirements in evaluation.	L3
CO3	Analyze clinical study design and risk–benefit assessment.	L4
CO4	Interpret preclinical data and assess clinical significance.	L4

Syllabus:

Unit No	Content	Lecture Hrs/contact Hrs
UNIT I	Definition and scope of clinical evaluation, Objectives and significance in healthcare product development, Distinction between clinical evaluation, clinical investigation, and clinical trials, Life cycle approach to clinical evaluation, Global and Indian regulatory frameworks: CDSCO, USFDA, EMA, WHO	**15**
UNIT II	Process / Requirement to be followed Informed Consent Process, CRF, Patient screening, Inclusion and exclusion criteria, Randomization, Blinding, Recruitment (materials and methods), Retention and Compliance of study subjects, Ethics Committee Submission.	**12**
UNIT III	Stages of clinical evaluation (planning, appraisal, analysis, and reporting),Designing clinical evaluation plans and reports, Comparative evaluation and equivalence studies,Use of risk-benefit analysis in evaluation, Tools and checklists (e.g., GRADE, CONSORT, PRISMA)	**12**
UNIT IV	Preclinical Study HT screening, In-vitro and In-vivo studies, animal models of disease, teratogenicity, reproductive toxicity, mutagenicity, carcinogenicity, selection of initial human dose from animal data, Assessment Extrapolation of animal data to clinical situation; Clinical Significances, adverse event, serious adverse event, end point.	**15**

Suggested Books

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5

Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:	3	1	1	1	2	1	1	2	1	1
CO2:	2	2	2	1	1	2	2	3	1	2
CO3:	2	1	1	3	1	1	1	2	2	1
CO4:	2	2	3	1	1	2	1	3	1	

1 = Low, **2 = Moderate**, **3 = High** contribution

Program	**Master in Clinical Research**	**Semester-I**			
Course Name	**Pharma Regulatory Affairs**	**L**	**T**	**P**	**C**
Course Code	**MCR 106**	**3**	**1**	**0**	**4**

Course Objectives:

This course ensures that the students understand how:

1	To understand the principles and legal framework of Pharmacovigilance, including risk management and safety monitoring.
2	To gain knowledge of regulatory requirements for medicinal products and medical devices at global and Indian levels.
3	To understand clinical investigation and lifecycle management of medical devices and combination products.
4	To develop understanding of pharmaceutical regulatory affairs processes including CTD/ACTD and drug policy in India.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	**Outcome**	**BT Level**
CO1	Explain principles of Pharmacovigilance, adverse event reporting, risk management plans, and global PV guidelines.	L2
CO2	Apply regulatory guidelines for medicinal products, vaccines, herbal medicines, and pharmacovigilance	L3

	systems.	
CO3	Analyze regulatory frameworks and classification systems for medical devices, IVDs, and combination products.	L4
CO4	Evaluate regulatory requirements, CTD/ACTD submissions, drug policies, and compliance processes in global and Indian contexts.	L5

Syllabus:

Unit No	Content	ContactHrs
UNIT I	**Pharmacovigilance** Introduction to Pharmacovigilance and Good Medicine, Safety Specification and Risk Management Plan Drug Hypersensitivity ,Vision for Pharmacovigilance In Euroupe Monitoring Safety of Vaccines Pharmacovigilance in Emerging Countries The Safety of Herbal Medicines Bayesian Statistics and Pharmacovigilance Writing a Proper Adverse Event Report	**12**
UNIT II	**Guidelines on Pharmacovigilance for Medicinal Products** Legal Basics and structure of Volume 9A, Legal Framework for the Pharmacovigilance, The Roles of the various parties, Requirement of Pharmacovigilance systems, Monitoring of Compliance and Pharmacovigilance inspections, Requirement of Risk Management systems Requirement of periodic safety update Reports, EU guidelines and relevant terminology Templates.	**15**
UNIT III	**Regulatory aspects of Medical Devices** Medical Devices- Introduction, Definition, and Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals. History of Medical Device Regulation. Product Lifecycle of Medical Devices and Classification of Medical Devices IMDRF/GHTF. Introduction, Organizational Structure. Purpose and Functions. Regulatory Guidelines. Working Groups. Summary Technical Document (STED). Global Medical Device Nomenclature (GMDN), Ethics. Clinical Investigation of Medical Devices. Clinical Investigation Plan for Medical Devices.	**15**
UNIT IV	**Pharma Regulatory Affairs** Drug Regulatory Authorities, Regulations on alternative system of Medicine, Drug Policy in India, Regulatory Affairs Procession, Regulated and semi regulated countries, ACTD and CTD Global + Indian	**12**

Suggested Readings

Text Book/ 1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices

Ref. Book : 1 . Book by Gary Walsh and John J. Tobin
2.FDA Regulatory Affairs: Third Edition

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1	3	2				2	1	2		
CO2	3	3	1	1	1	3	2	2	1	3
CO3	3	3	2	2	1	3	2	2	1	
CO4	3	3	2	2	2	3	2	3	2	2
CO5	2	3	0	0	1	3	1	3	2	

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-I			
Course Name	Site Management Organization	L	T	P	C
Course Code	MCR 108	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	To understand the structure, functions, regulatory and ethical framework of Site Management Organizations (SMO) and clinical research sites.
2	To gain knowledge of clinical trial project planning, budgeting, vendor selection, quality management and sponsor responsibilities.
3	To understand investigator responsibilities, site preparation, ethics committee approval, and subject recruitment & retention processes.
4	To develop managerial and operational skills in monitoring, compliance, documentation, finance and logistics management in clinical trials.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the structure, functions, regulatory and ethical guidelines governing Site Management Organizations and clinical research sites.	L2
CO2	Apply principles of clinical trial project planning, budgeting, vendor management, quality systems and documentation from the sponsor's perspective.	L3
CO3	Analyze investigator responsibilities, site management processes, ethics committee approvals, and subject recruitment and retention strategies.	L4
CO4	Evaluate clinical trial monitoring, compliance systems, contract management, financial management and risk-based monitoring approaches.	L5

Syllabus:

Unit No	Content	Contact Hrs
UNIT I	**Introduction to Site Management Organization** Definition, Regulatory Guidelines, Ethical Guidelines, Site Management Services, Roles and Responsibilities of a Clinical Research Coordinator (CRC), SMO Business scenario, Risk based monitoring.	10

UNIT II	**The Sponsor's Perspective –I** Clinical Trial Project Planning Management Clinical Trial Project Planning and Resource Management, Total Quality Control Management System (TQCMS) in a Clinical Trial Project, Clinical Trial Master File & Documents Management	12
UNIT III	**The Sponsor's Perspective –II** Clinical Trial Vendors Selection & Services Management Clinical, Trial Investigators Selection & Regulator Management Clinical, Trial Cost & Project Budgeting Management, Clinical Trial Agreement & Contract Management**,** Clinical Trial Fund & Finance Management, Clinical Trial Supply Chain / Logistics Management, Clinical Trial Project Monitoring & Compliance Management.	15
UNIT IV	**The Investigator's Perspective** Clinical Site Preparation & Management, Clinical Trial Site Team Management , Clinical Trial Site Training Management, Clinical Trial Site Documents Management , Clinical Trial Site Budgeting & Fund Management, Ethics Committee & Regulatory , Approval Process; the Investigator's Obligations, Investigators' Meeting; the , Investigators Preparation & Management, Subjects Recruitment Process; Regulatory & Ethical Management, Subjects Retention & Study Compliance Management	15

Suggested Readings books

Text book/:1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ

Reference book 1. Clinical trials. Remedial 2006, by Wang D and Bakhai A (Ed).

Scheme of Evaluation:

Component	**Adopted for this Course**	**Duration**	**Weightage**	**Date & Time**	**Venue**	**Remarks**	**Levels**
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	3	2				2	2	2		2
CO2:	3	3	2	1	1	3	2	2	1	
CO3:	3	3	2	2	1	3	2	2	1	2
CO4:	3	3	2	2	2	3	2	3	2	

1 = Low, **2 = Moderate**, **3 = High** contribution.

SEMESTER II

Program	**Master in Clinical Research**	**Semester-II**			
Course Name	**Preclinical Evaluation of Drugs**	**L**	**T**	**P**	**C**
Course Code	**MCR 201**	**3**	**1**	**0**	**4**

Course Objectives:

This course ensures that the students understand how:

1	The principles, strategies and techniques involved in drug discovery, high throughput screening, genomics and preclinical models.
2	The pharmacological evaluation of drugs affecting CNS, gastrointestinal, respiratory, reproductive and other systems.
3	The principles of bioassays, biological standardization, cell culture techniques, transgenic models and alternatives to animal experimentation.
4	The principles of toxicology including acute, sub-acute, chronic toxicity studies, reproductive toxicity, genotoxicity, carcinogenicity and safety pharmacology.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the drug discovery process, high throughput screening, genomics, and preclinical evaluation methods used in new drug development.	L2
CO2	Apply pharmacological principles to evaluate CNS, gastrointestinal, respiratory, reproductive and anticancer drugs in preclinical models.	L3
CO3	Analyze bioassay methods, biological standardization procedures, cell culture techniques, transgenic models, and alternative screening methods.	L4
CO4	Evaluate toxicity studies including acute, chronic, reproductive, genotoxicity, carcinogenicity and s pharmacology parameters (ED50, LD50, TD).	L5

Unit. No.	Content	Contact Hrs
UNIT I	Introduction and Drug discovery process Principles, techniques and strategies used in drug discovery. High throughput screening, human genomics, Preclinical models employed in the screening of new drugs; Preclinical evaluation of drugs **a.**CNS Pharmacology: Sedatives, hypnotics, anxiolytics, antidepressants, Muscle relaxants (Central). CNS stimulations, anticonvulsants, antipsychotics, Noortropics, antiparkinsonian agents, Analgesics, antipyretics, anti-inflammatory agents and local anesthetics. **b**.Gastrointestinal drugs: Antiulcer agents, laxatives **c**.Respiratory pharmacology: bronchodilators, antitussives, **d.** Diuretics. **e.**Reproductive pharmacology: anti fertility agents **f.**Anticancer agents	**15**
UNIT II	Bioassays: Basic Principles of Bioassays **a.**Biological standardization of vaccines and sera: Pertussis vaccine, rabies vaccine and Plague vaccine. **b.** Cell culture technology: Animal cell culture – General requirements for establishing the animal cell culture, media, conditions and methods for cell cultures. Applications in Pharmacy. **c.** Alternatives to animal screening procedures, Cell-line, patch clamp technique, In- vitro models and molecular biology techniques. **d.** Concept of transgenic animals, knockout animals, nude animals, receptor, binding assays, principles of immunoassay, patch clamp techniques. **e.** Safety pharmacology studies	**15**
UNIT III	Principles of Toxicology, General Aspects Acute, sub-acute and chronic toxicity studies Systemic Toxicity Studies, Male Fertility Study, Female Reproduction and Developmental Toxicity Studies Local toxicity Allergenicity/Hypersensitivity Genotoxicity, Carcinogenicity, ED 50, LD50 and TD values	**12**
UNIT IV	Guidelines and Regulatory Agencies, CPCSEA, OECD, FDA, ICH, WHO and any latest guidelines. Used in India as well as globally.	**12**

Suggested Readings

Text Book

1, Evaluation of Drug Candidates for Preclinical Development:

Reference Book

1. Pharmacokinetics, metabolism,pharmaceutics, and Toxicology-Wiley

2, Drug Screening Methods-Preclinical evaluation of new drugs-S.K Gupta

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	3	2						1		
CO2:	3	3	2	2	1			1	2	
CO3:	3	3	2	3	2	1	1	1		
CO4:	3	3	2	3	2	2	2	1		3
CO5:				2	2		3		2	

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-II			
Course Name	Molecular Mechanism of Drug Action	L	T	P	C
Course Code	MCR 202	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	The fundamental principles of pharmacodynamics and pharmacokinetics including drug–receptor interactions, dose-response relationships and therapeutic index.
2	Molecular mechanisms of signal transduction pathways, receptor regulation, enzyme inhibition and drug metabolism.
3	The molecular basis of action of chemotherapeutic agents, antibiotics, antivirals, biologics and gene-regulating drugs
4	The molecular and cellular mechanisms of cancer including oncogenes, tumor suppressor genes, cell cycle regulation and targeted therapy.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the principles of pharmacodynamics, pharmacokinetics, receptor types, ligand binding, dose-response relationships and therapeutic index.	L2
CO2	Apply concepts of signal transduction pathways, enzyme inhibition, drug metabolism and receptor regulation in explaining drug action.	L3
CO3	Analyze molecular mechanisms of chemotherapeutic agents, antibiotics, antivirals, biologics and gene-regulating drugs.	L4
CO4	Analyze molecular mechanisms involved in cancer development including oncogenes, tumor suppressors, cell cycle regulation and growth factor signaling.	L4

Syllabus:

Unit No	Content	ContactHrs
UNIT I	Definition and classification of drugs, Basic principles of pharmacodynamics and pharmacokinetics, Drug-receptor interactions: types of receptors, ligand-binding concepts, Dose-response relationships, Therapeutic index and drug efficacy	**12**
UNIT II	Types of receptors: ion channels, GPCRs, enzyme-linked receptors, nuclear receptors, Signal transduction pathways: cAMP, cGMP, phosphoinositide pathway, MAPK, JAK/STAT, Second messengers and their role in cellular responses, Receptor desensitization and downregulation	**15**
UNIT III	Enzyme inhibition: competitive, non-competitive, uncompetitive, Drugs acting on metabolic enzymes (e.g., NSAIDs, ACE inhibitors), Prodrugs and enzyme activation, Drug metabolism and its role in drug action, Drugs affecting gene expression and transcription factors, Molecular mechanisms of chemotherapeutic agents and antibiotics, Mechanisms of action of antivirals and biologics, Role of molecular chaperones, ubiquitination, and proteasomal degradation in drug action	**15**

UNIT IV	Introduction to Cancer, Microtubule inhibitors, Stabilizing destabilizing Growth Factor, Cell Cycle, Oncogenes, Tumor Suppressor, Endocrine Therapy, Targeted Therapy, Tyrosine kinase inhibitors, Gleevec in CML & Mechanisms of resistance.	**12**

SuggestedReadings

Text Book/:

1. Molecular Mechanisms of Drug Action Book by Christopher J. Coulson

Scheme of Evaluation:

Component	**Adopted for this Course**	**Duration**	**Weightage**	**Date & Time**	**Venue**	**Remarks**	**Levels**
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:	3	2						1		3
CO2:	3	3	1	2	1			1		
CO3:	3	3	2	3	2	1	1	1		3
CO4:	3	3	2	3	2	1	1	1		

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	**Master in Clinical Research**	**Semester-II**			
Course Name	**Pharmacovigilance-I**	**L**	**T**	**P**	**C**
Course Code	**MCR 203**	**3**	**1**	**0**	**4**

Course Objectives:

This course ensures that the students understand how:

1	To understand the definition, scope, objectives, history and public health importance of pharmacovigilance along with key terminologies and stakeholder roles.
2	To gain knowledge of classification, mechanisms, risk factors, detection and assessment methods of adverse drug reactions (ADRs).
3	To understand the components of pharmacovigilance systems including ICSR, PSUR, signal detection, risk management and global/Indian reporting requirements.
4	To develop practical understanding of pharmacovigilance applications such as Argus Safety, MedDRA coding, case processing and safety report writing (PSUR, CSR).

Course Outcomes:
Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the scope, objectives, historical development, key terminologies and stakeholder roles in pharmacovigilance.	L2
CO2	Apply knowledge of ADR classification, mechanisms, risk factors and assessment methods in evaluating adverse drug reactions.	L3
CO3	Analyze pharmacovigilance systems including signal detection, risk management, expedited reporting and global/Indian regulatory frameworks.	L4
CO4	Evaluate pharmacovigilance applications such as Argus Safety case processing, MedDRA coding and preparation of PSUR/CSR reports.	L5

Syllabus

Unit No	Content	Contact Hrs
UNIT I	Definition, scope, and objectives of pharmacovigilance (PV), Historical development and milestones in pharmacovigilance, Importance of PV in public health and patient safety, Key terminologies: adverse drug reaction (ADR), adverse event (AE), signal, risk, benefit-risk ratio, Roles of stakeholders: WHO, regulatory agencies, pharmaceutical companies, healthcare professionals	**15**
UNIT II	Classification and types of ADRs (Type A–F), Mechanisms underlying ADRs, Risk factors for ADRs, Methods for detection and assessment of ADRs, Examples of common ADRs and case studies	**12**
UNIT III	Components of a pharmacovigilance system, Spontaneous reporting systems (SRS), Periodic safety update reports (PSURs), Individual case safety reports (ICSRs), Risk Management in Pharmacovigilance and Signal Detection , Risk Assessments & Managements, PV Database And Signal Detection, Expedited Reporting Criteria, Medical Evaluation Of AE Global andIndian	**15**
UNIT IV	Pharmacovigilance-Applications, Importance of Applications in Pharmacovigilance Introduction to Argus Safety, Case Report management steps in Argus safety MedDra, PSUR and CSR writing chief initiation proposed in pharmacovigilance as a dictionary and study report	**12**

SuggestedReadings

Text Book

1.. Pharmacovigilance for Beginners –Dr. S. Gunasakaran and R.Salhesh Kumar TatamaniMagalirCo-Operative Press, 2010 edition

2. Introduction to Pharmacopoeia CBS Publishers and Distributors 1991edition.

Reference

3. Mind maps of Pharmacovigilance Basics- Amrita Akhouri, 2015 edition.

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3

Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:	3	2				2	2	2		1
CO2:	3	3	1	2	1	2	2	1		
CO3:	3	3	2	3	2	3	2	2	1	2
CO4:	3	3	2	3	3	3	2	3	1	3

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	**Master in Clinical Research**	**Semester-II**			
Course Name	**Pharmacology-I**	**L**	**T**	**P**	**C**
Course Code	**MCR 204**	**3**	**1**	**0**	**4**

Course Objectives
This course ensures that the students understand how:

1	To understand the basic principles of pharmacology including pharmacokinetics, pharmacodynamics, drug receptors, biotransformation and drug regulation.
2	To gain knowledge of autonomic pharmacology including cholinergic and adrenergic drugs and their mechanisms of action.
3	To understand the pharmacological management of cardiovascular and renal disorders including hypertension, heart failure, arrhythmias and angina.
4	To develop understanding of drugs acting on smooth muscles including histamine, serotonin, eicosanoids, nitric oxide and anti-asthmatic agents.

Course Outcomes

Towards the end of the course, students will be able to:

CO	Outcome	BT Level
CO1	Explain the principles of pharmacokinetics, pharmacodynamics, drug-receptor interactions, drug metabolism and regulation of drugs.	L2
CO2	Apply knowledge of autonomic pharmacology to explain the mechanism of action and therapeutic uses of cholinergic and adrenergic drugs.	L3
CO3	Analyze the pharmacological basis of drugs used in cardiovascular and renal disorders including antihypertensives, antianginal, antiarrhythmic and diuretic agents.	L4
CO4	Evaluate the role of mediators such as histamine, serotonin, prostaglandins, nitric oxide and drugs used in asthma and smooth muscle disorders.	L5

Syllabus:

Unit No	Content	Contact Hrs
UNIT I	Basic principles of Pharmacology, Introduction to pharmacology, drug receptors and pharmacodynamics, pharmacokinetics and pharmacodynamics, rational dosing and the time of drug action, Drug Biotransformation, Development and Regulation of Drugs.	**15**
UNIT II	**Autonomic Drugs** Introduction to Autonomic pharmacology, Cholinoceptor activating and Cholinesterase- Inhibiting drugs, Cholinoceptor-Blocking drugs, Adrenoceptor-Activating and other sympathomimetic drugs, Adrenoreceptor	**15**
UNIT III	**Cardiovascular- Renal Drugs** Antihypertensive agents, Vasodilators and the treatment of Angina pectoris, Drugs used in Heart Failure, Agents Used in Cardiac arrhythmias, Diuretic Agents.	15
UNIT IV	Drugs with Important actions on Smooth muscles Histamines, Serotonin and the ergot alkaloids, Vasoactive peptides, the Eicosanoids, prostaglandins, thromboxane's, leukotrienes, and related compounds, Nitric oxide and Drugs used in asthma.	15

SuggestedReadings

Text Book/:

1. K.D Tripathi's – Essentials of Medical Pharmacology edition 6th

Reference Book :

1. Ansel's – Pharmaceutical Dosage forms and Drug Delivery System 8th edition3.Goodman and Gillman's- The Pharmacological Basics of Therapeutics, 5th edition.

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

Course Outcome (CO)	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	3	2				1		1		1
CO2:	3	3	1	2	1	1		1		1
CO3:	3	3	2	2	1	2	1	1		
CO4:	3	3	2	2	1	2	1	2		1

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-II			
Course Name	Designing of Clinical Trials	L	T	P	C
Course Code	MCR E205	3	1	0	4

Course Objectives

This course ensures that the students understand how:

1. Understand various clinical trial designs and their applications.
2. Apply principles of clinical measurements including efficacy and safety endpoints.
3. Analyze randomization, blinding, and bias control techniques in clinical trials.
4. Evaluate special clinical trial models including QoL studies, multicenter trials, and single patient trials.
5. Recognize ethical issues, fraud, and misconduct in clinical research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain different types of clinical trial designs including prospective, retrospective, cross-sectional, longitudinal, parallel, crossover, sequential, factorial, and observational studies.	**L2**
CO2	Differentiate between QoL trials, multicenter trials, and single patient clinical trials including their advantages and limitations.	**L4**
CO3	Apply principles of efficacy criteria, safety endpoints, clinical scales, patient diaries, and selection of comparators in designing a clinical trial.	**L3**
CO4	Analyze different randomization techniques (simple, block, stratified, cluster, minimization) and blinding methods (open label, single, double, triple) including code breaking procedures.	**L4**
CO5	Evaluate sources of bias and issues of fraud and misconduct in clinical trials and suggest methods to minimize them.	**L5**

Syllabus

Unit No	Content	Contact Hrs
UNIT I	**Clinical Trial Design** Different types of trial design, Prospective Trials, Retrospective Clinical Trials, Cross- Sectional v/s Longitudinal trials, Parallel Designs, Cross Over designs , Sequential Designs, Factorial Designs, Observational Studies , Quality of Life Studies	12
UNIT II	Future of QoL Trials, Multicenter Trials- Advantages and Disadvantages ,Golden Rules, Administrative Considerations, Single Patient Clinical Trials, Purpose of Single Clinical Trials, Types of Single Patient trial designs, Trials in Special Population-Elderly, Children, Surgical Trials, Types of Surgical Trials.	12
UNIT III	**Clinical Measurements** Types of Efficacy Criteria, Efficacy Endpoints, Clinical Scales, Visual Analog Scales, Patient Diaries, Choosing Efficacy Parameters, Safety Endpoints, Choice of Comparator Active and Passive , Historical and Concurrent, No control , Sources of Bias-Subject Bias, Investigator bias , Selection Bias , Instrument Bias, Publication Bias.	15
UNIT IV	**Binding and Randomization** Simple, Block, Stratified, Cluster, Unequal Minimization, Blinding – Open Label, Single, Double and Triple Blinding, Breaking the code/Blind in Clinical Trials; Fraud and Misconduct in Clinical trials.	12

SuggestedReadings

Text Book/:

1. Clinical Trials Design, ICRI

2. Fundamentals of Clinical Trials"

ReferenceBook:

1. Lawrence M. Friedman, Curt D. Furberg, David L. DeMets

Scheme of Evaluation:

Component	Adopted for this	Duration	Weightage	Date &	Venue	Remarks	Levels

	Course			Time			
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:			2	2				3	2	3
CO2:			3	2			2	2	2	
CO3:			2	2		2		3	2	3
CO4:			3	2			1	3	2	
CO5:	2	1	2	3			1	2	2	1

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	**Master in Clinical Research**	**Semester-II**			
Course Name	**GMP & GLP**	**L**	**T**	**P**	**C**
Course Code	**MCR E207**	**3**	**1**	**0**	**4**

Course Objectives

This course ensures that the students understand how:

1. Understand fundamental concepts of Quality Systems including QA, QC, GMP, and GLP.
2. Explain regulatory requirements and international guidelines governing pharmaceutical manufacturing and laboratory practices.
3. Apply GMP principles in manufacturing, documentation, validation, and quality assurance.
4. Apply GLP principles in laboratory organization, study conduct, and data management.
5. Develop regulatory compliance awareness for inspections, audits, and quality management systems.

Course Outcomes:
Towards the end of the course, the students will be able to:

CO No.	Outcome	BT Level
CO1	Explain the concepts of Quality, QA, QC, GMP, and GLP including their historical development and regulatory significance.	L2
CO2	Differentiate between GMP and GLP and describe the roles of international regulatory bodies such as WHO, USFDA, EMA, ICH, and OECD.	L4
CO3	Apply GMP requirements in areas such as personnel, premises, equipment, sanitation, documentation, production controls, validation, and audits.	L3
CO4	Apply GLP principles in laboratory organization, study planning, SOP implementation, data recording, reporting, and archiving.	L3
CO5	Evaluate regulatory compliance systems including inspections, self-audits, quality assurance programs, and OECD GLP principles.	L5

Syllabus:

Unit No.	Content	ContactHrs

UNIT I	Introduction to Quality Systems Concepts of Quality, Quality Assurance (QA), and Quality Control (QC), Overview of GMP and GLP: definitions, objectives, and historical background, Importance and necessity of regulatory compliance, Differences and similarities between GMP and GLP	10
UNIT II	Good Manufacturing Practices (GMP) – I Elements of GMP: personnel, premises, equipment, Sanitation and hygiene, Documentation and record-keeping: SOPs, batch records, logbooks, Raw materials management and inventory control, Warehousing and distribution	10
UNIT III	Good Manufacturing Practices (GMP) – II Production and in-process controls, Packaging and labeling controls, Quality control and assurance, Validation: process, equipment, cleaning, analytical method validation, Self-inspection and audits	12
UNIT IV	Good Laboratory Practices (GLP) – I Principles and scope of GLP, Organization and personnel responsibilities, Facilities: layout, environment, and equipment requirements, Standard Operating Procedures (SOPs) in laboratories, Study plans and conduct of non-clinical studies	12
UNIT V	Good Laboratory Practices (GLP) – II Data recording, storage, and archiving, Quality assurance in GLP studies, Test and reference items: characterization and handling, reporting of study results, Regulatory inspections and compliance (OECD	12

Suggested Readings

Text Book/

1. S.H.willig,M,M. Tuckeman and W.S. Hitchings, "Good manufacturing practices for

pharmaceuticals", Drugs and Pharm.sci. series, vol.16, Marcel Dekker Inc., N.Y
2. B.T.Lo ftus & R.A.Nash, "Pharmaceutical process validation", drugs and pharm sci.series,vol.23, Maarcel dekker inc.,N.Y.

Reference Book

1. S.bolton, Pharmaceutical statistics: practical & clinical applications",Drugs and Pharm.sci.series,vol.25, Marcel dekker Inc.,N.Y.4.G.S, Banker & C.T.Rhodes

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix:

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	3			2				2		
CO2:	3			3				2		2
CO3:	2			2		2	2			2
CO4:	1			3				3	2	2
CO5:	2		1	2				2	2	3

1 = Low, **2 = Moderate**, **3 = High** contribution.

SEMESTER III

Program	Master in Clinical Research	Semester-III			
Course Name	Pharmacovigilance-II	L	T	P	C
Course Code	MCR 301	3	1	0	4

Course Objectives
This course ensures that the students understand how:

1. Understand the principles, history, and objectives of Pharmacovigilance (PV).
2. Explain adverse drug reactions (ADRs), signal detection, and risk management strategies.
3. Apply methods for case processing, safety reporting, and data management in PV systems.
4. Analyze pharmacovigilance practices in special populations and post-marketing settings.
5. Evaluate emerging trends such as artificial intelligence, real-world evidence, and global harmonization in PV

.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO No.	Outcome	BT level
CO1	Explain the concepts, history, objectives, and key definitions of pharmacovigilance including ADRs, SAEs, and post-marketing surveillance.	L2
CO2	Analyze signal detection methods (PRR, ROR, Bayesian methods), risk assessment, risk management plans (RMP), and risk minimization measures (RMM).	L4
CO3	Apply principles of Individual Case Safety Reports (ICSRs), aggregate reporting, case processing workflow, and safety database management (e.g., ARISg, Argus, VigiBase).	L3
CO4	Evaluate pharmacovigilance practices in special populations (pediatric, geriatric, pregnancy), vaccines, biologics, herbal medicines, and PASS studies.	L5
CO5	Assess the role of artificial intelligence, automation, real-world evidence, big data analytics, and global harmonization in the future of pharmacovigilance.	L5

Syllabus

Unit No	Content	ContactHrs
UNIT I	Overview on Pharmacovigilance Introduction to Pharmacovigilance, Key Definitions in Pharmacovigilance, Pharmacovigilance Historical Perspective, Pharmacovigilance need and Objectives, Pharmacovigilance and Pharmacogenetics, Current methods in Pharmacovigilance. Adverse drug reactions and SAE criteria, Post Marketing Surveillance, Global and Indian	12
UNIT II	Signal detection methods: quantitative and qualitative, Use of statistical tools in signal detection (e.g., PRR, ROR, Bayesian methods), Risk assessment and risk management planning (RMP), Risk minimization measures (RMM), Role of data mining in signal detection	12
UNIT III	Individual Case Safety Reports (ICSRs) and aggregate reporting, Data flow in pharmacovigilance systems, Case processing workflow: data entry, triage, assessment, Safety databases: ARISg, Argus, VigiBase, Data validation and quality assurance	12
UNIT IV	PV in pediatric and geriatric populations, PV for vaccines and biologics, Pharmacovigilance in pregnancy and lactation,Herbal medicines and traditional products, Post-authorization safety studies (PASS)	12
UNIT V	Artificial intelligence and automation in PV, Real-world evidence (RWE) and big data analytics, Social media and patient-reported outcomes, Global harmonization and future challenges, Career opportunities and industry practices	10

SuggestedReadings

Text Book:

1.Pharmacovigilance for Beginners –Dr. S. Gunasakaran and R.Salhesh Kumar TatamaniMagalirCo-Operative Press, 2010 edition

2. Introduction to Pharmacopoeia CBS Publishers and Distributors 1991 edition.

ReferenceBook: .

1.Highlights of Pharmacovigilance – P.G Yeolo, DhanalakshmiIyer, 2013 edition.

2..Mind maps of Pharmacovigilance Basics- Amrita Akhouri, 2015 edition.

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	2		2	3				3	2	2
CO2:		2				2	3		2	
CO3:				2	3		2			
CO4:	2		2	3	2		3	3	3	
CO5:	3			3			3			2

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-III			
Course Name	Pharmacology-II	L	T	P	C
Course Code	MCR 302	3	1	0	4

Course Objectives
This course ensures that the students understand how:

1. Understand pharmacological principles of drugs used in hematological, inflammatory, cardiovascular, renal, infectious, and gastrointestinal disorders.
2. Explain mechanisms of action, therapeutic uses, adverse effects, and drug interactions of major drug classes.
3. Apply rational prescribing principles in special populations including pediatric, geriatric, and prenatal patients.
4. Analyze chemotherapeutic agents including antibiotics, antiparasitic drugs, anticancer drugs, and immunopharmacological agents.
5. Evaluate toxicological principles, management of poisoning, and drug safety considerations.

Course Outcomes
Towards the end of the course, the students will be able to:

CO No.	Outcome	BT level
CO1	Explain the pharmacology of drugs used in anemia, coagulation disorders, hyperlipidemia, inflammation, gout, and pain management.	L2
CO2	Analyze the mechanisms, spectrum of activity, resistance, and clinical use of chemotherapeutic agents including antibiotics, antiparasitic drugs, anticancer drugs, and immunopharmacological agents.	L4
CO3	Apply pharmacological knowledge of cardiovascular and renal drugs including antihypertensives, antianginals, antiarrhythmics, diuretics, and heart failure medications in therapeutic decision-making.	L3
CO4	Evaluate toxicological principles including heavy metal poisoning, chelation therapy, drug interactions, and management of poisoned patients.	L5
CO5	Apply rational prescribing principles and special pharmacological considerations in pediatric, geriatric, prenatal patients, dermatologic and gastrointestinal disorders, including vaccines and biologics.	L3

Syllabus:

Unit No.	Content	Contact Hrs

UNIT I	**Drugs used to treat diseases of the Blood, Inflammation and Gout** Agents used in Anemias Hematopoietic growth factors, drugs used in disorders of Coagulation, Agents used in Hyperlipidemia, Nonsteroidal anti-inflammatory drugs, disease-modifying antirheumatic drugs, Nonopioid analgesics and drugs used in Gout.	10
UNIT II	**Chemotherapeutics Drugs** Beta-Lactam and other Cell wall and Membrane active antibiotics, Tetracyclines, Macrolides, clindamycin, chloramphenicol and streptogramins, aminoglycosides and spectinomycin, sulphonamides, trimethoprim, and Quinolones, introduction to antiparasitic chemotherapy, antiprotozoal drugs, Clinical pharmacology of the anthelmintic drugs, Cancer Chemotherapy and Immunopharmacology.	12
UNIT III	Drugs Acting on Cardiovascular and Renal Systems Antihypertensive agents, Antianginal and antiarrhythmic drugs, Drugs used in heart failure, Diuretics and their pharmacological classifications.	10
UNIT IV	**Toxicology** Introduction to toxicology, heavy metal intoxication and chelators, Management of the poisoned patient, therapeutic and toxic potential of over-the counter agents, important drug interactions and their Mechanisms.	12
UNIT V	**Special Topics** Special aspects of prenatal and pediatric pharmacology, Special aspects of Geriatric pharmacology, dermatologic pharmacology, drugs used in the treatment of gastrointestinal diseases, botanicals and nutritional supplements, rational prescribing and prescription writing, vaccines, Immuno Globulin and other complex biologic products.	12

Text Book
Book:
1. K.D Tripathi's – Essentials of Medical Pharmacology edition 6th

Reference
1. Ansel's – Pharmaceutical Dosage forms and Drug Delivery System 8th edition Goodman and Gillman's- The Pharmacological Basics of Therapeutics, 5thedition.

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:					3		2			
CO2:	1	2	2		3		2			
CO3:					2		3	1		
CO4:			2	1	2				1	
CO5:		2			3		2	2	2	2

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-III			
Course Name	Advanced Clinical Data Management	L	T	P	C
Course Code	MCR 303	3	1	0	4

Course Objectives:
This course ensures that the students understand how:

1. Understand the fundamentals of Clinical Data Management (CDM), data standards, and regulatory requirements.
2. Apply principles of CRF design, electronic data capture, and database management in clinical research.
3. Analyze data validation, query management, coding systems, and discrepancy handling processes.
4. Evaluate regulatory compliance, data integrity, privacy requirements, and audit processes in CDM.
5. Explore emerging technologies such as AI, machine learning, and real-world data integration in clinical data management.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO No.	Outcome	BT Level
CO1	Explain the concepts, terminology, importance, and standards of Clinical Data Management including CDISC standards (CDASH, SDTM).	L2
CO2	Apply principles of CRF design (paper & electronic), CRF annotation, data mapping, EDC systems, and database design with edit checks.	L3
CO3	Analyze query management, discrepancy handling, SAE reconciliation, coding systems (MedDRA, WHO Drug Dictionary), and data validation processes.	L4
CO4	Evaluate regulatory requirements (ICH-GCP, 21 CFR Part 11, EMA, FDA, DCGI), data integrity, privacy laws (HIPAA, GDPR), and compliance audits in CDM.	L5
CO5	Assess the role of SAS, R, Python, AI/ML, real-world data (RWD/RWE), and emerging technologies in modern clinical data management and career	L5

	applications.	

Syllabus

Unit No.	Content	Contact Hrs
UNIT I	Introduction to CDM, Basic terminologies, definitions and Glossary, Importance of CDM, Data privacy, Data Management standards in clinical research, Design and development of data collection instruments, electronic data capture.	12
UNIT II	Design of Case Report Forms (paper and electronic),CRF annotation and data mapping,Electronic Data Capture (EDC) systems: features and vendors (e.g., Medidata Rave, Oracle Clinical, Open Clinica),Source data verification (SDV) and remote monitoring, Clinical data standards (CDISC: CDASH, SDTM)	12
UNIT III	Database design and edit checks, Query management and resolution process, Data validation techniques, Handling discrepancies and audit trails, SAE reconciliation and coding (MedDRA, WHO Drug Dictionary)	10
UNIT IV	Regulatory guidelines (ICH-GCP, 21 CFR Part 11, EMA, FDA, DCGI), Data integrity and compliance audits, Risk-based monitoring and data quality metrics, Data lock, freeze, and archival, Privacy and confidentiality (HIPAA, GDPR)	10
UNIT V	Use of SAS, R, and Python in data analysis and CDM, AI and machine learning applications in data management, Real-world data (RWD) and real-world evidence (RWE), Integration of clinical data with lab, imaging, and omics data, Career roles in CDM: CRA, CDM Associate, Data Manager, Clinical Data Scientist	12

SuggestedReadings

TextBook:

1. Practical Guide to Clinical Data Management, Susanne Prokscha, Thirdedition.

2.Clinical Analytics and Data Management for the DNP, Martha L Sylvia andMary F. Terhaar

ReferenceBook:

1.Guide to GCP for Clinical Data Management- Mark Elsley, 2017. 4.Clinical Data Management,-R.K Rondel and Sheila A. Varley

2.Validating Clinical Trial Data Reporting with SAS – Carol Matthews and Brian Shilling

Scheme of Evaluation:

Component	**Adopted for this Course**	**Duration**	**Weightage**	**Date & Time**	**Venue**	**Remarks**	**Levels**
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:		2				1				
CO2:		2		1		2				
CO3:		2				3				
CO4:	1	2		3		2			1	1
CO5:	1		2	2		1	2	2	1	2

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-III			
Course Name	Clinical Trial Management	L	T	P	C
Course Code	MCR 304	3	1	0	4

Course Objectives:

This course ensures that the students understand how:

1	Understand the basic concepts, history, objectives, and phases of clinical trials.
2	Learn the principles of protocol development and different clinical trial study designs.
3	Gain knowledge about clinical trial operations, site management, and project management.
4	Understand monitoring, auditing, and safety reporting procedures in clinical trials.
5	Develop awareness about regulatory requirements, quality systems, and ethical aspects of clinical research.

Course Outcomes:

Towards the end of the course, the students will be able to:

CO	Outcome	BT Level
CO1	Explain the fundamentals, phases, and stakeholders involved in clinical trials.	L2
CO2	Describe and apply different study designs, protocol components, and informed consent procedures.	L3
CO3	Analyze clinical trial operations, site management, budgeting, and project management activities.	L4
CO4	Evaluate monitoring methods, safety reporting (AE, SAE, SUSAR), and audit processes in clinical trials.	L5
CO5	Apply regulatory guidelines and quality principles for proper conduct, documentation, and reporting of clinical trials.	L3

Unit No	Content	Contact Hrs
UNIT I	Introduction to Clinical Trials Definition, objectives, and types of clinical trials, History and evolution of clinical trials, Phases of clinical trials (Phase I–IV), Roles and responsibilities of stakeholders: Sponsor, CRO, Investigator, Ethics Committee, Overview of ICH-GCP and Schedule Y	12
UNIT II	Protocol Development and Study Design Components of a clinical trial protocol, Study designs: Randomized controlled trials, blinding, crossover, factorial designs, Sample size estimation and statistical considerations, Trial registration and	12
UNIT III	Clinical Trial Operations and Project Management Site selection and initiation, Budgeting and financial management in trials, Trial project management tools and techniques, Clinical Trial Agreements (CTAs)	10
UNIT IV	Monitoring, Auditing, and Safety Reporting Types and responsibilities of clinical trial monitoring, Source data verification (SDV) and risk-based monitoring, Adverse Event (AE), Serious Adverse Event (SAE), and SUSAR reporting, Data and Safety	10
UNIT V	Regulatory and Quality Aspects Regulatory frameworks: ICH-GCP, US FDA, EMA, DCGI, MHRA,Trial master file (TMF) and essential documents, Quality assurance (QA) and quality control (QC) in clinical trials, Clinical trial data handling and confidentiality, End-of-trial activities: close-out, data lock, and reporting	12

SuggestedReadings

Text Book/:

1. Guide to Clinical Trials, Bert Spilker, 1991 (Now 3rd edition)
2. Good Clinical Practice for Clinical Research in India, ICRI Publication

3. Good Clinical Practices, ICRI Government Published 2011
4. Principles of Clinical Research, ICRI Publication ICRI

ReferenceBook

1. Ethical guidelines for Biomedical Research on Human Subject, ICRI Government Published 2000
2. Schedule Y Ministry of Health & Family Welfare Notification, ICRI Government Published ICRI
Practical Guide Clinical Management - Nancy J Stark February 2004

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	P10
CO1:	3			2				3		
CO2:			2	2				2		2
CO3:	3			3				3		
CO4:		2	3	2	2				3	
CO5:						2	2	2	2	3

_1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	Master in Clinical Research	Semester-III			
Course Name	Research Methodology	L	T	P	C
Course Code	MCR E305	3	1	0	4

Course Objectives:
This course ensures that the students understand how:

1. To understand the fundamental concepts, objectives, and types of research.
2. To develop skills in problem formulation, hypothesis construction, and research design.
3. To understand sampling techniques and tools for data collection.
4. To apply appropriate statistical techniques for data analysis and interpretation.
5. To develop competency in writing and presenting a structured research report.

Course Outcomes:
Towards the end of the course, the students will be able to:

CO No.	Outcome	BT level
CO1	Explain the basic concepts, objectives, types, and process of research.	L2
CO2	Formulate research problems, identify variables, construct hypotheses, and design appropriate research plans.	L3
CO3	Apply sampling techniques and design questionnaires/interviews for data collection.	L3
CO4	Analyze research data using appropriate statistical tools such as correlation, regression, ANOVA, and multivariate techniques.	L4
CO5	Prepare and present a structured research report following standard formats and referencing styles.	L6

Syllabus

Unit No.	Content	Contact Hrs
UNIT I	**Introduction to Research Methods:** Definition of research, role and objectives of research, applications and types of research, research process and steps in it. Collecting and reviewing the literature, conceptualization and Formulation of a research problem, Identifying variables, constructing hypothesis, Synopsis.	15
UNIT II	**Research Design:** Meaning, need and features of good research design, Types of Research Designs, Basic Principles of Experimental Designs, Design of experiments, and Synopsis design for research topic	12
UNIT III	**Design of Sample Survey:** Census V/s Sample enumerations, objectives and principles of sampling, Types of sampling, Sampling and Non-sampling errors. Designing Questionnaires and interview. Determination of the sample size.	12
UNIT IV	**Data Collection & Analysis:** Primary & secondary data, Validity and Reliability of data collection procedures, data preparation, exploratory data analysis, parametric and nonparametric tests, correlation and regression analysis, ANOVA, Multivariate Techniques.	12
UNIT V	**Research Report** :Type of research report- contents, Steps in drafting, Editing and evaluating the final draft, Styles for figures, tables, text, quoting of reference and bibliography, Use and format of appendices- Indexing, Structure and presentation of research report	12

Suggested Book
Text Book

1.Research Methodology, CR Kothari
2.Responsible Conduct of Research, Adil E.Shamoo

Scheme of Evaluation:

Component	Adopted for this Course	Duration	Weightage	Date & Time	Venue	Remarks	Levels
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5

Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:	3	2	2						2	1
CO2:	2	3	2			2			2	1
CO3:	2	2	3	2		2	2		2	1
CO4:		3				3			1	1
CO5:		2	2			2			3	2

1 = Low, **2 = Moderate**, **3 = High** contribution.

Program	**Master in Clinical Research**	**Semester-III**			
Course Name	**Advanced Medical Writing**	**L**	**T**	**P**	**C**
Course Code	**MCR E306**	**3**	**1**	**0**	**4**

Course Objectives:

This course ensures that the students understand how:

1: Find out the roles and responsibilities of a medical writer.

2: Explain the regulations and ethics in medical writing.
3: Build up the writing skills for publication medical content.
4: Examine clinical study report and how to do documentation in medical writing.
5: Discuss the importance of principles of clinical research and clinical trial documentseffectively.

Course Outcomes:
Towards the end of the course, the students will be able to:

CO No.	Outcome	BT level
CO1	Explain the definition, scope, importance, roles, and ethical principles of medical writing including plagiarism and data confidentiality.	L2
CO2	Prepare regulatory and clinical documents such as protocols, ICF, IB, CSR (ICH E3), CTD modules, CRFs, and safety narratives in compliance with guidelines.	L3
CO3	Develop scientific manuscripts including original articles, review articles, case reports, abstracts, and systematic reviews following CONSORT, PRISMA, and STROBE guidelines.	L6
CO4	Analyze and respond to peer-review comments and apply appropriate referencing styles (Vancouver, APA, AMA) using reference management tools.	L4
CO5	Design medical marketing materials, patient education content, and technical healthcare documents using appropriate terminology (ICH-GCP, MedDRA, MeSH) and writing tools.	L6

Syllabus

Unit No.	Content	Contact Hrs
UNIT I	Definition, scope, and importance of medical writing, Roles and responsibilities of medical writers, Types of medical writing: Regulatory, Scientific, Marketing, Educational, Skills required: language, scientific understanding, analytical thinking, Ethical considerations and plagiarism.	12
UNIT II	Regulations and Ethics in Medical Writing Writing protocols, Investigator's Brochure (IB), Informed Consent Forms (ICF), Clinical Study Reports (CSRs) – structure and guidelines (ICH E3), Safety narratives and pharmacovigilance documents, Common Technical Document (CTD) and eCTD modules, Case Report Forms (CRFs) and SAE reports.	10

UNIT III	Journal article writing: Original article, review, short communication, case report, Abstracts, Literature review and systematic reviews, CONSORT, PRISMA, and STROBE guidelines, Peer-review process and responding to reviewers. Different types of Review writing.	12
UNIT IV	Medical marketing content: brochures, product monographs, slide decks, Patient education leaflets and newsletters, technical writing for medical devices and healthcare software, medical journalism and news writing	10
UNIT V	Referencing styles: Vancouver, APA, AMA, Using EndNote, Mendeley, Zotero, Grammar tools: Grammarly, Hemingway, PerfectIt, ICH-GCP, MedDRA, MeSH terminology usage, Copyright, data protection, and confidentiality.	10

Textbooks

1. "Essentials of Medical Writing" – *Robert B. Taylor*

References:

1. "Medical Writing: A Guide for Clinicians, Educators, and Researchers" – *Robert B. Taylor*
2. How to Write and Publish a Scientific Paper *Authors: Barbara Gastel & Robert A. Day*

Scheme of Evaluation:

Component	**Adopted for this Course**	**Duration**	**Weightage**	**Date & Time**	**Venue**	**Remarks**	**Levels**
Mid term	☑	1.5hr	15			Traditional	Levels 2 to 5
Assignment	☑		15			Group	Levels 1 to 5
Surprise Quiz	☑	30mins	10			MCQ	Level 1to 3
Case Study	☑	2hr	10			Discussion & Presentation	Levels 3 to 5
Comprehensive Exam	☑	3hr	50			Traditional	Levels 1 to 5

Course Outcomes – Program Outcomes (CO – PO) Articulation Matrix

PO → CO ↓	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**
CO1:	3			2						2

CO2:	3			3				2		2
CO3:										3
CO4:	2		2	2		2			2	3
CO5:	2		3	3			2	3	2	3

1 = Low, **2 = Moderate**, **3 = High** contribution.

SEMESTER IV

Program	**Master in Clinical Research**	**Semester-IV**			
Course Name	**Internship or Major Project Report Dissertation**	**L**	**T**	**P**	**C**
Course Code	**MCR 401**			**44**	**22**