Annexure-3.30 of AC-51/2025

PROGRAM OUTCOME (POs)

Course Code	M.Sc. Clinical Research	
PO1	Demonstrate comprehensive knowledge of clinical research methodologies, study design, biostatistics, and ethical principles to conduct high-quality research.	Knowledge
PO2	Apply national and international regulatory guidelines, ethical considerations, and Good Clinical Practice (GCP) standards in clinical trials and patient safety.	Knowledge & skill, decision making
PO3	Develop, implement, and analyze clinical research studies using appropriate methodologies, statistical tools, and data interpretation techniques.	Methodology & Analytical Skills
PO4	Exhibit leadership, teamwork, and effective communication skills in interdisciplinary clinical research settings for successful project management and collaboration.	Professional & Interpersonal Skills
PO5	Utilize critical thinking, innovation, and evidence-based approaches to address challenges in drug development, clinical trials, and healthcare advancements.	Critical Thinking & Problem-Solving

Course Outcomes (COs)

Course Code	
	SEMESTER I
MCR 101 T	**History & Fundamentals of Clinical Research**
CO1	Explain the Evolution of Clinical Research
CO2	Demonstrate Understanding of Ethical and Regulatory Frameworks
CO3	Evaluate the Impact of Landmark Clinical Trials
CO4	Apply Principles of Good Clinical Practice (GCP)
CO5	Identify Key Figures in Clinical Research
CO6	Assess Societal and Ethical Challenges in Clinical Research
CO7	Understand Pharmacovigilance and Safety Monitoring
MCR 102 T	**Clinical Research Methodologies**
CO1	Explain the fundamental concepts, definitions, and applications of research.
CO2	Classify research types based on applications, objectives, and paradigms.
CO3	Describe and explain the eight-step research process.
CO4	Formulate a research problem, design, and proposal.
CO5	Demonstrate data collection methods, sampling techniques, and instrument construction.
CO6	Analyze literature to identify research gaps and synthesize findings.
CO7	Develop skills for structuring and writing research reports effectively.
MCR 103 T	**Pharmacology- I**
CO1	Explain the history, sources, drug development process, and principles of pharmacology.
CO2	Describe different routes of drug administration and the pharmacokinetics of drugs.
CO3	Explain drug interactions, mechanisms of action, and adverse drug reactions (ADRs).
CO4	Classify and explain the pharmacology of cholinergic, anticholinergic, adrenergic, and antiadrenergic drugs.
CO5	Explain the action and uses of skeletal muscle relaxants and local anesthetics.
CO6	Apply pharmacological concepts in clinical settings and drug therapy decision-making.
CC 001 T	**Research Methodology & Biostatistics (Core Course)**
CO1	Explain the fundamentals of research methodology, including research design, data collection, and analysis.
CO2	Develop skills in presenting and critically analyzing research articles.
CO3	Demonstrate methods for presenting data effectively using tables, graphs, and charts.
CO4	Compute and interpret mean, median, mode, variance, and standard deviation.
CO5	Explain hypothesis testing concepts, including Chi-square tests, ANOVA, and non-parametric tests.
CO6	Utilize SPSS and other statistical tools for biostatistical analysis.
MCR 105 CP	**MCR Directed Clinical Education-I**
CO1	Build a robust theoretical foundation, enabling students to understand healthare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.
CO 2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.
CO 3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.
CC 001 P	**Research Methodology & Biostatistics (Core Course)**
CO1	Explain the fundamentals of research methodology, including research design, data collection, and analysis.
CO2	Develop skills in presenting and critically analyzing research articles.
CO3	Demonstrate methods for presenting data effectively using tables, graphs, and charts.
CO4	Compute and interpret mean, median, mode, variance, and standard deviation.
CO5	Explain hypothesis testing concepts, including Chi-square tests, ANOVA, and non-parametric tests.
CO6	Utilize SPSS and other statistical tools for biostatistical analysis.
	Discipline Specific Elective Theory
DSE 001 T	**Ethics in Clinical Research**
CO1	Explain the historical development of clinical research ethics, including key ethical guidelines
CO2	Identify and analyze legal liabilities, investigator responsibilities, and compensation-related obligations in clinical research.
CO3	Describe the role of CIOMS, NIH, and ICMR guidelines in ethical clinical research.
CO4	Explain the function and significance of IRB/IEC/ERB in clinical trials.
CO5	Analyze the ethics review process and the importance of informed consent in clinical trials.
CO6	Evaluate the ethical and legal aspects of informed consent and patient information documentation.
DSE 002 T	**Different Systems of Medicine**
CO1	Explain the origins, evolution, and significance of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy.
CO2	Describe the fundamental principles of disease prevention and treatment in different systems of medicine.
CO3	Examine how traditional practices align with or differ from modern medical approaches.
CO4	Identify key medicinal plants used in different systems and their therapeutic applications.
CO5	Discuss recent advances in validating traditional medicine and US botanical drug development.
CO6	Assess how globalization has influenced Ayurveda and other traditional systems.
	SEMESTER II
MCR 106 T	**Drug Analysis**
CO1	Explain the principles and types of analytical methods used in drug analysis.
CO2	Identify and describe various laboratory apparatus used in drug analysis.
CO3	Explain the theory, mathematical concepts, and principles behind IR absorption spectroscopy.
CO4	Analyze and interpret IR spectra for organic and inorganic compounds.
CO5	Explain the working of Single Beam and Double Beam spectrometers and their applications.
CO6	Evaluate the applications of IR spectroscopy in the qualitative and quantitative analysis of drugs.
CO7	Discuss advanced techniques such as ATR, Non-dispersive IR, and Polythermal Beam Deflection Spectroscopy.
MCR 107 T	**Clinical Research Guidelines I**
CO1	Explain the CDSCO guidelines for bioavailability & bioequivalence studies and their significance in clinical research.
CO2	Analyze the ethical principles from the World Medical Association's Declaration of Helsinki.
CO3	Interpret regulatory requirements for clinical trials in India as per Schedule Y.
CO4	Describe the principles of GCP and their role in ensuring ethical and high-quality clinical trials.
CO5	Compare international regulatory guidelines for BA/BE studies in veterinary and human medicine.
CO6	Examine the importance of clinical safety data management and periodic safety update reports.

MCR 108 T	**Pharmacology II**
CO1	Explain the mechanism of action, uses, and side effects of diuretics and antidiuretics.
CO2	Describe the pharmacology of drugs used for peptic ulcers, emetics, antiemetics, constipation, and diarrhea.
CO3	Classify and explain the mechanisms of action of beta-lactam antibiotics, tetracyclines, aminoglycosides, and chloramphenicol.
CO4	Understand the pharmacokinetics, pharmacodynamics, and clinical applications of anti-TB and antileprotic drugs.
CO5	Identify different antifungal and antiviral drugs and their applications in treating infections.
CO6	Explain the mode of action, resistance mechanisms, and therapeutic uses of drugs for malaria and urinary tract infections.
MCR 110 CP	**MCR Directed Clinical Education-II**
CO1	Build a robust theoretical foundation, enabling students to understand healthcare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.
CO 2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.
CO 3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.
	Discipiline Specific Elective Theory
DSE 003 T	**Epidemiological Principles Relevant to Clinical Research**
CO1	Explain mortality and morbidity indicators, and their relevance in epidemiological studies.
CO2	Analyze different types of bias (study, response, information, interviewer, site selection, measurement, and confounding) in research.
CO3	Interpret diagnostic tests, screening tests, and prognostic tests using an evidence-based approach.
CO4	Understand the principles and applications of pharmacoepidemiological studies in clinical settings.
CO5	Explain how molecular and genetic epidemiology contribute to clinical research.
CO6	Discuss the impact of race, ethnicity, social class, and culture on clinical research methodologies.
DSE 004 T	**Clinical Trial Operations**
CO1	Explain the process of selecting trial sites, investigators, and vendors.
CO2	Describe the responsibilities of sponsors, institutions, coordinators, and investigators.
CO3	Identify essential trial documents (protocol, CRF, ICD, investigator brochure, agreements).
CO4	Manage recruitment, site master file, SOPs, and regulatory compliance.
CO5	Understand the role of monitors, auditors, and data monitoring committees.
CO6	Develop strategies to handle unexpected challenges during clinical trials.
CO7	Explain procedures for trial close-out, database lock, ethics committee submissions, and publication.
	Skill Ehancement Course
SEC 001 T	**Alternatives in Toxicity Testing**
CO1	Explain CPCSEA guidelines and ethical considerations in animal testing.
CO2	Describe the principles of Reduce, Refine, Replace, and Rehabilitate in animal research.
CO3	Analyze non-mammalian and non-animal models used for toxicity testing.
CO4	Explain the standard procedures for reporting animal trial data.
CO5	Assess the effectiveness of alternative testing methods such as the Draize test.
CO6	Describe the use of zebrafish, drosophilae, and C. elegans in toxicity studies.
SEC 002 T	**One Health (NPTEL)**
CO1	A comprehensive understanding of One Health & role in global health challenges, emphasizing interconnectedness among human, animal, and environmental health.
CO2	Topics include research ethics, disease surveillance, and successes in controlling emerging infectious diseases.
CO3	Students explore disease emergence, transmission, antimicrobial resistance, and food safety, gaining insights into effective public health strategies.

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
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CO PO Mapping
Programe - M.Sc. Clinical Research
Semester I and II

PO1	Demonstrate comprehensive knowledge of clinical research methodologies, study design, biostatistics, and ethical principles to conduct high-quality research.
PO2	Apply national and international regulatory guidelines, ethical considerations, and Good Clinical Practice (GCP) standards in clinical trials and patient safety.
PO3	Develop, implement, and analyze clinical research studies using appropriate methodologies, statistical tools, and data interpretation techniques.
PO4	Exhibit leadership, teamwork, and effective communication skills in interdisciplinary clinical research settings for successful project management and collaboration.
PO5	Utilize critical thinking, innovation, and evidence-based approaches to address challenges in drug development, clinical trials, and healthcare advancements.

PO Mapping same with correlation level 3,2,1 The notation of 1 - low, 2 - moderate , 3 - high

Semester	Course / Course Code	Course Outcome	Course Outcome	Knowledge	Knowledge & skill, decision making	Methodology & Analytical Skills	Professional & Interpersonal Skills	Critical Thinking & Problem-Solving	Average
				PO1	P02	PO3	PO4	PO5	
Semester 1	History and Fundamentals of Clinical Research (MCR 101 T)	CO1	Explain the Evolution of Clinical Research	3	2	1	1	3	2.0
		CO2	Demonstrate Understanding of Ethical and Regulatory Frameworks	3	0	0	0	0	0.6
		CO3	Evaluate the Impact of Landmark Clinical Trials	3	0	0	3	0	1.2
		CO4	Apply Principles of Good Clinical Practice (GCP)	0	3	0	0	0	0.6
		CO5	Identify Key Figures in Clinical Research	3	3	3	3	3	3.0
		CO6	Assess Societal and Ethical Challenges in Clinical Research	0	0	0	0	3	0.6
		CO7	Understand Pharmacovigilance and Safety Monitoring	3	0	3	0	2	1.6
		Average		2.1	1.1	1.0	1.0	1.6	1.4
	Clinical Research Methodologies (MCR 102 T)	CO1	Explain the fundamental concepts, definitions, and applications of research.	3	0	0	3	0	1.2
		CO2	Classify research types based on applications, objectives, and paradigms.	3	3	2	2	3	2.6
		CO3	Describe and explain the eight-step research process.	3	0	0	3	0	1.2
		CO4	Formulate a research problem, design, and proposal.	0	0	3	0	0	0.6
		CO5	Demonstrate data collection methods, sampling techniques, and instrument construction.	3	3	3	2	1	2.4
		CO6	Analyze literature to identify research gaps and synthesize findings.	3	2	0	3	0	1.6
		CO7	Develop skills for structuring and writing research reports effectively.	0	0	3	0	3	1.2
		Average		2.1	1.1	1.6	1.9	1.0	1.5
	Pharmacology - I (MCR 103 T)	CO1	Explain the history, sources, drug development process, and principles of pharmacology.	3	0	0	3	0	1.2
		CO2	Describe different routes of drug administration and the pharmacokinetics of drugs.	3	0	0	3	0	1.2
		CO3	Explain drug interactions, mechanisms of action, and adverse drug reactions (ADRs).	3	0	0	3	0	1.2
		CO4	Classify and explain the pharmacology of cholinergic, anticholinergic, adrenergic, and antiadrenergic drugs.	3	0	0	3	0	1.2

		CO5	Explain the action and uses of skeletal muscle relaxants and local anesthetics.	3	0	0	3	0	1.2
		CO6	Apply pharmacological concepts in clinical settings and drug therapy decision-making.	3	0	0	3	3	1.8
		Average		3.0	0.0	0.0	3.0	0.5	1.3
	Research Methodology & Biostatistics (core Course) (CC 001 T)	**CO1**	Students will demonstrate the ability to design a research study, including the formulation of research questions, hypothesis generation, and selection of appropriate study design (e.g., experimental, observational).	0	0	3	3	2	1.6
		Average		0.0	0.0	3.0	3.0	2.0	1.6
	MCR Directed Clinical Education - I (MCR 105 CP)	**CO1**	Build a robust theoretical foundation, enabling students to understand healthare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.	3	3	3	2	2	2.6
		CO 2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.	2	3	3	2	2	2.4
		CO 3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.	3	3	2	1	2	2.2
		Average		2.7	3.0	2.7	1.7	2.0	2.4
	Ethics in Clinical Research (DSE 001 T)	**CO1**	Explain the historical development of clinical research ethics, including key ethical guidelines	3	3	0	3	0	1.8
		CO2	Identify and analyze legal liabilities, investigator responsibilities, and compensation-related obligations in clinical research.	3	3	2	2	0	2.0
		CO3	Describe the role of CIOMS, NIH, and ICMR guidelines in ethical clinical research.	0	3	0	0	0	0.6
		CO4	Explain the function and significance of IRB/IEC/ERB in clinical trials.	0	3	0	0	0	0.6
		CO5	Analyze the ethics review process and the importance of informed consent in clinical trials.	0	3	3	2	3	2.2
		CO6	Evaluate the ethical and legal aspects of informed consent and patient information documentation.	0	3	0	0	3	1.2
		Average		1.0	3.0	0.8	1.2	1.0	1.4
	Different Systems of Medicine (DSE 002 T)	**CO1**	Explain the origins, evolution, and significance of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy.	3	3	0	2	0	1.6
		CO2	Describe the fundamental principles of disease prevention and treatment in different systems of medicine.	3	0	0	3	0	1.2
		CO3	Examine how traditional practices align with or differ from modern medical approaches.	3	0	0	3	0	1.2
		CO4	Identify key medicinal plants used in different systems and their therapeutic applications.	3	0	0	3	0	1.2
		CO5	Discuss recent advances in validating traditional medicine and US botanical drug development.	3	0	0	3	0	1.2
		CO6	Assess how globalization has influenced Ayurveda and other traditional systems.	3	0	0	2	2	1.4
		Average		3.0	0.5	0.0	2.7	0.3	1.3
Semester II	**Drug Analysis (MCR 106 T)**	**CO1**	Explain the principles and types of analytical methods used in drug analysis.	3	0	0	3	0	1.2
		CO2	Identify and describe various laboratory apparatus used in drug analysis.	3	0	0	3	0	1.2
		CO3	Explain the theory, mathematical concepts, and principles behind IR absorption spectroscopy.	3	0	0	3	0	1.2
		CO4	Analyze and interpret IR spectra for organic and inorganic compounds.	3	0	0	3	3	1.8
		CO5	Explain the working of Single Beam and Double Beam spectrometers and their applications.	3	0	0	3	0	1.2

	CO6	Evaluate the applications of IR spectroscopy in the qualitative and quantitative analysis of drugs.	3	0	0	3	0	1.2
	CO7	Discuss advanced techniques such as ATR, Non-dispersive IR, and Polythermal Beam Deflection Spectroscopy.	3	0	0	3	0	1.2
	Average		3.0	0.0	0.0	3.0	0.4	1.3
Clinical Research Guidelines I (MCR 107 T)	**CO1**	Explain the CDSCO guidelines for bioavailability & bioequivalence studies and their significance in clinical research.	3	3	0	2	0	1.6
	CO2	Analyze the ethical principles from the World Medical Association's Declaration of Helsinki.	3	3	0	2	0	1.6
	CO3	Interpret regulatory requirements for clinical trials in India as per Schedule Y.	3	3	0	2	0	1.6
	CO4	Describe the principles of GCP and their role in ensuring ethical and high-quality clinical trials.	3	3	0	2	0	1.6
	CO5	Compare international regulatory guidelines for BA/BE studies in veterinary and human medicine.	3	3	0	2	0	1.6
	CO6	Examine the importance of clinical safety data management and periodic safety update reports.	3	3	0	2	2	2.0
	Average		3.0	3.0	0.0	2.0	0.3	1.7
Pharmacology - II (MCR 108 T)	**CO1**	Explain the mechanism of action, uses, and side effects of diuretics and antidiuretics.	3	0	0	3	0	1.2
	CO2	Describe the pharmacology of drugs used for peptic ulcers, emetics, antiemetics, constipation, and diarrhea.	3	0	0	3	0	1.2
	CO3	Classify and explain the mechanisms of action of beta-lactam antibiotics, tetracyclines, aminoglycosides, and chloramphenicol.	3	0	0	3	0	1.2
	CO4	Understand the pharmacokinetics, pharmacodynamics, and clinical applications of anti-TB and antileprotic drugs.	3	0	0	3	0	1.2
	CO5	Identify different antifungal and antiviral drugs and their applications in treating infections.	3	0	0	3	0	1.2
	CO6	Explain the mode of action, resistance mechanisms, and therapeutic uses of drugs for malaria and urinary tract infections.	3	0	0	3	0	1.2
	Average		3.0	0.0	0.0	3.0	0.0	1.2
MCR Directed Clinical Education - II (MCR 110 CP)	**CO1**	Build a robust theoretical foundation, enabling students to understand healthare practices, disease management, and patient care, thereby empowering them to make informed decisions and adapt to evolving medical technologies.	3	3	0	0	1	1.4
	CO2	Emphasize hands-on training, ensuring proficiency in clinical procedures, diagnostic techniques, and the use of advanced medical equipment. This practical exposure will bridge the gap between theory and practice, enhancing students' confidence and competence in delivering quality patient care.	0	0	0	0	0	0.0
	CO3	Focus on developing professionalism, empathy, ethical conduct, teamwork, and communication skills—key traits for holistic patient care and effective collaboration in interdisciplinary healthcare teams.	3	3	0	0	1	1.4
	Average		2.0	2.0	0.0	0.0	0.7	0.9
Discipiline Specific Elective Theory								
Epidemiological Principles Relevant to Clinical Research (DSE 003 T)	**CO1**	Explain mortality and morbidity indicators, and their relevance in epidemiological studies.	3	0	3	2	0	1.6
	CO2	Analyze different types of bias (study, response, information, interviewer, site selection, measurement, and confounding) in research.	3	0	0	2	2	1.4
	CO3	Interpret diagnostic tests, screening tests, and prognostic tests using an evidence-based approach.	3	0	3	2	2	2.0
	CO4	Understand the principles and applications of pharmacoepidemiological studies in clinical settings.	3	0	3	3	0	1.8
	CO5	Explain how molecular and genetic epidemiology contribute to clinical research.	3	0	3	3	0	1.8
	CO6	Discuss the impact of race, ethnicity, social class, and culture on clinical research methodologies.	3	0	2	2		1.8

		Average		3.0	0.0	2.3	2.3	0.8	1.7
	Clinical Trial Perations (DSE 004 T)	**CO1**	Explain the process of selecting trial sites, investigators, and vendors.	3	3	0	2	0	1.6
		CO2	Describe the responsibilities of sponsors, institutions, coordinators, and investigators.	3	3	0	2	0	1.6
		CO3	Identify essential trial documents (protocol, CRF, ICD, investigator brochure, agreements).	3	3	0	2	0	1.6
		CO4	Manage recruitment, site master file, SOPs, and regulatory compliance.	3	3	0	2	0	1.6
		CO5	Understand the role of monitors, auditors, and data monitoring committees.	3	3	0	2	0	1.6
		CO6	Develop strategies to handle unexpected challenges during clinical trials.	3	3	0	2	0	1.6
		Average		3.0	3.0	0.0	2.0	0.0	1.6
	Skill Ehancement Course								
	Alrenative in Toxicity Testing (SEC 001 T)	**CO1**	Explain CPCSEA guidelines and ethical considerations in animal testing.	3	3	0	2	0	1.6
		CO2	Describe the principles of Reduce, Refine, Replace, and Rehabilitate in animal research.	3	3	0	2	0	1.6
		CO3	Analyze non-mammalian and non-animal models used for toxicity testing.	3	3	0	2	0	1.6
		CO4	Explain the standard procedures for reporting animal trial data.	3	3	0	2	0	1.6
		CO5	Assess the effectiveness of alternative testing methods such as the Draize test.	3	3	0	2	0	1.6
		CO6	Describe the use of zebrafish, drosophilae, and C. elegans in toxicity studies.	3	3	0	2	0	1.6
		Average		3.0	3.0	0.0	2.0	0.0	1.6
	One Health (NPTEL) (SEC 002 T)	**CO1**	A comprehensive understanding of One Health & role in global health challenges, emphasizing interconnectedness among human, animal, and environmental health.	0	0	0	3	3	1.2
		CO2	Topics include research ethics, disease surveillance, and successes in controlling emerging infectious diseases.	3	3	0	0	0	1.2
		CO3	Students explore disease emergence, transmission, antimicrobial resistance, and food safety, gaining insights into effective public health strategies.	3	0	0	0	3	1.2
		Average		2.0	1.0	0.0	1.0	2.0	1.2

PROGRAM OUTCOME	
Course Code	**M.Sc. CLINICAL RESEARCH**
PO1	Demonstrate comprehensive knowledge of clinical research methodologies, study design, biostatistics, and ethical principles to conduct high-quality research.
PO2	Apply national and international regulatory guidelines, ethical considerations, and Good Clinical Practice (GCP) standards in clinical trials and patient safety.
PO3	Develop, implement, and analyze clinical research studies using appropriate methodologies, statistical tools, and data interpretation techniques.
PO4	Exhibit leadership, teamwork, and effective communication skills in interdisciplinary clinical research settings for successful project management and collaboration.
PO5	Utilize critical thinking, innovation, and evidence-based approaches to address challenges in drug development, clinical trials, and healthcare advancements.
COURSE OUTCOMES	
Course Code	**M.Sc. MEDICAL BIOTECHNOLOGY**
SEMESTER III	
MCR 111 T	**Clinical Research Guidelines-II**
CO1	Explain the principles of international and national clinical research guidelines (ICH-GCP, Schedule Y, CDSCO, FDA, EMA, WHO).
CO2	Interpret ethical requirements, informed consent processes, and subject protection measures in line with guidelines.
CO3	Apply regulatory guidelines in protocol design, submission, and conduct of clinical trials.
CO4	Compare and contrast global regulatory requirements and their implications on multinational trials.
CO5	Demonstrate professional communication and teamwork in preparing regulatory submissions and SOPs.
CO6	Critically evaluate the impact of regulatory guidelines on drug development, patient safety, and clinical research quality.
MCR 112 T	**Pharmacovigilance Materiovigilance**
CO1	Explain the principles, scope, and importance of pharmacovigilance and materiovigilance in ensuring patient safety.
CO2	Describe regulatory requirements and guidelines for pharmacovigilance and materiovigilance in India and globally (e.g., CDSCO, WHO, USFDA, EMA).
CO3	Apply methods of adverse drug reaction (ADR) reporting, signal detection, and risk assessment in pharmacovigilance.
CO4	Analyze pharmacovigilance and materiovigilance databases, software, and tools used for data management and signal detection.
CO5	Demonstrate teamwork and communication skills in preparing safety reports, regulatory submissions, and patient information documents.
CO6	Critically evaluate real-world case studies of drug/device safety issues, regulatory actions, and global safety surveillance.

MCR 113 T	Introduction to Database & Various Software in Clinical Data Management
CO1	Explain the fundamentals of clinical databases, data flow, and their role in clinical research.
CO2	Describe the features and applications of commonly used CDM software (Oracle Clinical, Medidata Rave, OpenClinica, RedCap, SAS).
CO3	Apply principles of data entry, query management, and validation using simulated databases or software tools.
CO4	Analyze data management processes including CRF design, edit checks, data cleaning, and audit trails in compliance with GCP.
CO5	Demonstrate teamwork and communication skills in preparing mock CDM workflows, project reports, and presentations.
CO6	Critically evaluate the importance of data integrity, security, and regulatory compliance in clinical databases and software systems.
MCR 114 T	**Pharmacoeconomics and Health Technology Assessment**
CO1	Explain the basic concepts of pharmacoeconomics, cost types, and health technology assessment.
CO2	Describe national and international perspectives on HTA and its role in healthcare decision-making and policy.
CO3	Apply pharmacoeconomic evaluation methods (CMA, CEA, CUA, CBA) to clinical and healthcare scenarios.
CO4	Analyze cost-effectiveness studies and HTA reports to assess the value of drugs, devices, and interventions.
CO5	Demonstrate teamwork and communication skills in preparing and presenting pharmacoeconomic evaluations.
CO6	Critically evaluate the ethical, social, and policy implications of pharmacoeconomics and HTA on healthcare systems and patient access.
MCR 115 T	**Medical Writing**
CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.
CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.
CO3	Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH).
CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.
CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.
CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.
MCR 116	**Research Project / Dissertation**
CO1	Formulate a research problem by reviewing scientific literature and identifying knowledge gaps in field of clinical research.
CO2	Design and execute research projects using appropriate methodologies, tools, and techniques relevant to biomedical research.
CO3	Demonstrate proficiency in designing ,handling & conducting advanced research project including clinical trials
CO4	Critically analyze and interpret experimental data using appropriate statistical and computational tools.
CO5	Adhere to ethical standards in biomedical research, including biosafety, data integrity, and responsible reporting.
CO6	Communicate research findings effectively through well-structured dissertation writing, presentations, and potential publications.

CO7	Work independently and collaboratively to solve research challenges and manage time efficiently during the project.
CO8	Develop a research-oriented mindset that prepares them for higher studies, industrial R&D, or academic research careers
MCR 117 P	**Practical's/Hands-on Training**
CO1	Apply the principles of clinical trial design, documentation, and ethical conduct by preparing essential research documents such as study protocols, case report forms, and informed consent forms.
CO2	Demonstrate the ability to record, code, and manage clinical and safety data using appropriate databases, coding systems (MedDRA/ICD), and electronic data capture tools following GCP and regulatory standards
CO3	Develop competency in medical and regulatory writing by preparing clinical study reports, safety summaries, and scientific manuscripts suitable for regulatory submission or publication.
CO4	Analyze and interpret economic, legal, and intellectual property aspects of pharmaceuticals and medical devices to support evidence-based decision-making and compliance with national and international regulations.
CO5	Integrate multidisciplinary knowledge to perform comprehensive clinical research management tasks, including documentation, safety evaluation, ethical review, and communication of findings in a professional and compliant manner.
MCR 118 P	**Medical Writing**
CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.
CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.
CO3	Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH).
CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.
CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.
CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.
SEMESTER IV	
MCR 119 T	**Clinical Research Management**
CO1	Explain the principles, scope, and processes of clinical research management, including trial planning and execution.
CO2	Describe the roles of sponsors, CROs, investigators, and ethics committees in trial management.
CO3	Apply project management tools and techniques in budgeting, resource allocation, site management, and monitoring
CO4	Analyse challenges in clinical trial operations including recruitment, retention, risk management, and quality assurance
CO5	Demonstrate teamwork, leadership, and communication skills in coordinating trial teams and preparing project deliverables
CO6	Critically evaluate the ethical, regulatory, and strategic dimensions of managing multinational and multicentric clinical trials.
MCR 120 T	**Pharmaceutical Organisations & Pharmaceutical Jurisprudence in India**
CO1	Explain the structure and role of the Indian pharmaceutical industry and CROs in clinical research.
CO2	Describe the regulatory framework governing pharmaceuticals and CRO operations in India.

CO3	Analyze the business models, organizational structure, and functional areas of CROs.
CO4	Compare Indian CROs with global CROs in terms of opportunities, challenges, and quality standards.
CO 5	Evaluate the contribution of CROs in innovation, drug development, and healthcare delivery in India in Comparison with global CROs in terms of opportunities, challenges, and quality standards.
CO 6	Explain the principles of pharmaceutical legislation in India, including the Drugs and Cosmetics Act, Pharmacy Act, and related rules.
CO 7	Apply legal requirements in clinical trial conduct, drug approval, import–export, and manufacturing processes.

CO8	Critically evaluate ethical and legal challenges in drug regulation, pricing, marketing, and patient safety.
MCR 121 T	**Bioethics IPR and Biosafety**
CO1	Evaluate ethical concerns in biomedical and biotechnological practices.
CO2	Understand different types of IPR and their applications.
CO3	Apply various national and international guidelines in biomedical and health research.
MCR 122 T	**Communication Skills**
CO1	Explain the principles of effective verbal, non-verbal, and written communication in professional and clinical research settings.
CO 2	Demonstrate the ability to draft professional documents including emails, reports, SOPs, and regulatory submissions.
CO 3	Apply presentation skills using modern tools (PowerPoint, posters, infographics) for communicating research outcomes.
CO4	Analyze communication barriers and develop strategies for effective cross-cultural and interdisciplinary communication.
CO5	Demonstrate teamwork, leadership, and negotiation skills in group activities, discussions, and project settings.
CO6	Critically evaluate the role of communication in patient engagement, informed consent, conflict resolution, and stakeholder management.
MCR 116	**Research Project / Dissertation**
CO1	Formulate a research problem by reviewing scientific literature and identifying knowledge gaps in field of clinical research.
CO2	Design and execute research projects using appropriate methodologies, tools, and techniques relevant to biomedical research.
CO3	Demonstrate proficiency in designing ,handling & conducting advanced research project including clinical trials
CO4	Critically analyze and interpret experimental data using appropriate statistical and computational tools.
CO5	Adhere to ethical standards in biomedical research, including biosafety, data integrity, and responsible reporting.
CO6	Communicate research findings effectively through well-structured dissertation writing, presentations, and potential publications.
CO7	Work independently and collaboratively to solve research challenges and manage time efficiently during the project.
CO8	Develop a research-oriented mindset that prepares them for higher studies, industrial R&D, or academic research careers.
MCR 123 P	**Internship/Training (Clinical/ Industrial)**
CO1	Apply theoretical knowledge of clinical research design, pharmacovigilance, and regulatory frameworks to real-world clinical or industrial settings, demonstrating practical competency and ethical conduct.
CO2	Develop proficiency in clinical documentation and data management, including source data verification, CRF entry, query resolution, and adherence to GCP and SOPs during project execution.
CO3	Demonstrate effective professional communication, teamwork, and coordination with multidisciplinary teams including investigators, monitors, regulatory personnel, and data managers.

CO4	Analyze and interpret clinical, safety, and operational data to support evidence-based decision-making and contribute to ongoing or completed clinical studies, pharmacovigilance activities, or regulatory submissions.
CO5	Reflect critically on the industrial/clinical work experience, identifying areas for skill enhancement, understanding organizational workflows, and integrating ethical, regulatory, and quality perspectives into professional practice.

PO1 **Demonstrate comprehensive knowledge of clinical research methodologies, study design, biostatistics, and ethical principles to conduct high-quality research.**

PO2 **Apply national and international regulatory guidelines, ethical considerations, and Good Clinical Practice (GCP) standards in clinical trials and patient safety.**

PO3 **Develop, implement, and analyze clinical research studies using appropriate methodologies, statistical tools, and data interpretation techniques.**

PO4 **Exhibit leadership, teamwork, and effective communication skills in interdisciplinary clinical research settings for successful project management and collaboration.**

PO5 **Utilize critical thinking, innovation, and evidence-based approaches to address challenges in drug development, clinical trials, and healthcare advancements.**

	Course / Course Code	Course Outcome	Course Outcome	Apply Biotechnological Knowledge in Medical Sciences	Conduct Independent and Collaborative Research	Utilize Advanced Molecular and Analytical Techniques	Solve Complex Biological Problems	Demonstrate Ethical and Professional Responsibility	Average
				PO1	PO2	PO3	PO4	PO5	
SEMESTER 3	Clinical Research Guidelines-II MCR 111 T	CO1	Explain the principles of international and national clinical research guidelines (ICH-GCP, Schedule Y, CDSCO, FDA, EMA, WHO).	3	1	3	2	1	2.0
		CO2	Interpret ethical requirements, informed consent processes, and subject protection measures in line with guidelines.	3	1	3	2	1	2.0
		CO3	Apply regulatory guidelines in protocol design, submission, and conduct of clinical trials.	3	1	3	2	1	2.0
		CO4	Compare and contrast global regulatory requirements and their implications on multinational trials.	3	2	1	3	3	2.4
		CO5	Demonstrate professional communication and teamwork in preparing regulatory submissions and SOPs.	3	2	1	3	3	2.4
		CO6	Critically evaluate the impact of regulatory guidelines on drug development, patient safety, and clinical research quality.	3	1	1	1	3	1.8
			Average	3	1.33	2	2.17	2	2.1
	Pharmacovigilance & Materiovigilance MCR 112 T	CO1	Explain the principles, scope, and importance of pharmacovigilance and materiovigilance in ensuring patient safety.	3	3	3	3	3	3.0
		CO2	Describe regulatory requirements and guidelines for pharmacovigilance and materiovigilance in India and globally (e.g., CDSCO, WHO, USFDA, EMA).	3	3	2	1	3	2.4
		CO3	Apply methods of adverse drug reaction (ADR) reporting, signal detection, and risk assessment in pharmacovigilance.	3	3	3	3	3	3.0
		CO4	Analyze pharmacovigilance and materiovigilance databases, software, and tools used for data management and signal detection.	3	2	1	3	1	2.0
		CO5	Demonstrate teamwork and communication skills in preparing safety reports, regulatory submissions, and patient information documents.	3	2	1	3	1	2.0

	CO6	Critically evaluate real-world case studies of drug/device safety issues, regulatory actions, and global safety surveillance.	2	2	1	3	3	2.2
		Average	2.833333333	2.50	1.83	2.666666667	2.333333333	2.43
Introduction to Database & Various Software in Clinical Data Management MCR 113 T	CO1	Explain the fundamentals of clinical databases, data flow, and their role in clinical research.	3	2	2	3	1	2.2
	CO2	Describe the features and applications of commonly used CDM software (Oracle Clinical, Medidata Rave, OpenClinica, RedCap, SAS).	3	3	2	3	3	2.8
	CO3	Apply principles of data entry, query management, and validation using simulated databases or software tools.	3	3	3	3	3	3.0
	CO4	Analyze data management processes including CRF design, edit checks, data cleaning, and audit trails in compliance with GCP.	3	3	2	2	2	2.4
	CO5	Demonstrate teamwork and communication skills in preparing mock CDM workflows, project reports, and presentations.	3	3	2	2	2	2.4
	CO6	Critically evaluate the importance of data integrity, security, and regulatory compliance in clinical databases and software systems.	3	1	2	1	3	2.0
		Average	3	2.5	2.166666667	2.33	2.333333333	2.5
Pharmacoeconomics and Health Technology Assessment MCR 114 T	CO1	Explain the basic concepts of pharmacoeconomics, cost types, and health technology assessment.	3	2	1	2	3	2.2
	CO2	Describe national and international perspectives on HTA and its role in healthcare decision-making and policy.	3	3	1	2	3	2.4
	CO3	Apply pharmacoeconomic evaluation methods (CMA, CEA, CUA, CBA) to clinical and healthcare scenarios.	1	2	1	1	2	1.4
	CO4	Analyze cost-effectiveness studies and HTA reports to assess the value of drugs, devices, and interventions.	1	1	1	1	3	1.4
	CO5	Demonstrate teamwork and communication skills in preparing and presenting pharmacoeconomic evaluations.	1	1	1	1	3	1.4
	CO6	Critically evaluate the ethical, social, and policy implications of pharmacoeconomics and HTA on healthcare systems and patient access.	1	1	1	2	3	1.6
		Average	1.666666667	1.666666667	1.00	1.50	2.833333333	1.7
Medical Writing MCR 115 T	CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.	3	3	2	3	2	2.6
	CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.	3	3	3	3	3	3.0
	CO3	Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH).	3	3	3	3	3	3.0
	CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.	3	3	2	3	3	2.8
	CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.	2	2	1	1	3	1.8
	CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.	2	2	1	2	2	1.8
		Average	2.666666667	2.666666667	2	2.5	2.666666667	2.5
	CO1	Formulate a research problem by reviewing scientific literature and identifying knowledge gaps in field of clinical research.	3	3	3	2	1	2.4

Research Project / Dissertation MCR116	**CO2**	Design and execute research projects using appropriate methodologies, tools, and techniques relevant to biomedical research.	2	1	1	3	3	2.0
	CO3	Demonstrate proficiency in designing ,handling & conducting advanced research project including clinical trials	2	1	3	3	3	2.4
	CO4	Critically analyze and interpret experimental data using appropriate statistical and computational tools.	3	3	2	2	3	2.6
	CO5	Adhere to ethical standards in biomedical research, including biosafety, data integrity, and responsible reporting.	3	3	2	2	3	2.6
	CO6	Communicate research findings effectively through well-structured dissertation writing, presentations, and potential publications.	3	3	2	2	3	2.6
	CO7	Work independently and collaboratively to solve research challenges and manage time efficiently during the project.	3	3	2	2	3	2.6
	CO8	Develop a research-oriented mindset that prepares them for higher studies, industrial R&D, or academic research careers	3	3	3	3	3	3.0
		Average	2.8	2.5	2.3	2.4	2.8	2.5
Practical's/Hands-on Training MCR117 P	**CO1**	Apply the principles of clinical trial design, documentation, and ethical conduct by preparing essential research documents such as study protocols, case report forms, and informed consent forms.	3	1	2	1	3	2.0
	CO2	Demonstrate the ability to record, code, and manage clinical and safety data using appropriate databases, coding systems (MedDRA/ICD), and electronic data capture tools following GCP and regulatory standards	3	3	2	2	3	2.6
	CO3	Develop competency in medical and regulatory writing by preparing clinical study reports, safety summaries, and scientific manuscripts suitable for regulatory submission or publication.	3	2	2	1	2	2.0
	CO4	Analyze and interpret economic, legal, and intellectual property aspects of pharmaceuticals and medical devices to support evidence-based decision-making and compliance with national and international regulations.	3	3	2	2	3	2.6

		CO5	Integrate multidisciplinary knowledge to perform comprehensive clinical research management tasks, including documentation, safety evaluation, ethical review, and communication of findings in a professional and compliant manner.	3	2	2	2	3	2.4
			Average	3.0	2.3	2.0	1.7	2.8	2.4
	Medical Writing MCR 118 P	CO1	Explain the scope, principles, and ethical aspects of medical writing in clinical research and healthcare.	1	2	1	1	3	1.6
		CO2	Describe the structure and content of key clinical research documents such as protocols, informed consent forms, study reports, and regulatory submissions.	2	2	1	1	2	1.6
		CO3	Apply scientific writing skills to prepare clear, concise, and well-structured research documents in compliance with regulatory standards (ICMJE, GCP, ICH).	3	1	1	1	3	1.8
		CO4	Analyze published scientific articles, clinical trial reports, and regulatory documents for quality, accuracy, and compliance.	3	1	1	1	3	1.8
		CO5	Demonstrate professional communication and teamwork in preparing manuscripts, posters, and presentations for conferences and publications.						
		CO6	Critically evaluate real-world challenges in medical writing such as plagiarism, authorship disputes, data transparency, and publication ethics.	3	1	1	1	3	1.8
			Average	2.0	1.7	1.0	1.0	2.7	1.7
SEMESTER 4	Clinical Research Management MCR 119 T	CO1	Explain the principles, scope, and processes of clinical research management, including trial planning and execution.	3	3	2	3	2	2.6
		CO2	Describe the roles of sponsors, CROs, investigators, and ethics committees in trial management.	3	3	3	3	3	3.0
		CO3	Apply project management tools and techniques in budgeting, resource allocation, site management, and monitoring	3	3	3	3	3	3.0
		CO4	Analyse challenges in clinical trial operations including recruitment, retention, risk management, and quality assurance	3	3	2	3	3	2.8
		CO5	Demonstrate teamwork, leadership, and communication skills in coordinating trial teams and preparing project deliverables	2	2	1	1	3	1.8
		CO6	Critically evaluate the ethical, regulatory, and strategic dimensions of managing multinational and multicentric clinical trials.	2	2	1	2	2	
			Average	2.666666667	2.67	2.00	2.5	2.67	2.5
	Pharmaceutical Organisations & Pharmaceutical Jurisprudence in India MCR 120 T	CO1	Explain the structure and role of the Indian pharmaceutical industry and CROs in clinical research.	3	3	3	3	3	3.0
		CO2	Describe the regulatory framework governing pharmaceuticals and CRO operations in India.	3	3	3	3	3	3.0
		CO3	Analyze the business models, organizational structure, and functional areas of CROs.	3	2	3	3	3	2.8
		CO4	Compare Indian CROs with global CROs in terms of opportunities, challenges, and quality standards.	3	2	2	2	3	2.4
		CO5	Evaluate the contribution of CROs in innovation, drug development, and healthcare delivery in India in Comparison with global CROs in terms of opportunities, challenges, and quality standards.	2	2	2	3	2	2.2
		CO6	Explain the principles of pharmaceutical legislation in India, including the Drugs and Cosmetics Act, Pharmacy Act, and related rules.	3	3	3	3	3	3.0
		CO7	Apply legal requirements in clinical trial conduct, drug approval, import–export, and manufacturing processes.	2	2	2	3	3	2.4

	CO8	Critically evaluate ethical and legal challenges in drug regulation, pricing, marketing, and patient safety.	2	2	2	2	3	2.2
		Average	2.6	2.4	2.5	2.8	2.9	2.6
Bioethics IPR and Biosafety MCR 121 T	CO1	Evaluate ethical concerns in biomedical and biotechnological practices.	3	3	2	3	2	2.6
	CO2	Understand different types of IPR and their applications.	3	3	3	3	3	3.0
	CO3	Apply various national and international guidelines in biomedical and health research.	3	3	3	3	3	3.0
		Average	3	3.00	2.67	3	2.67	2.9
Communication skills MCR 122 T	CO1	Explain the principles of effective verbal, non-verbal, and written communication in professional and clinical research settings.	3	3	3	3	3	3.0
	CO2	Demonstrate the ability to draft professional documents including emails, reports, SOPs, and regulatory submissions.	3	3	3	3	3	3.0
	CO3	Apply presentation skills using modern tools (PowerPoint, posters, infographics) for communicating research outcomes.	3	2	3	3	3	2.8
	CO4	Analyze communication barriers and develop strategies for effective cross-cultural and interdisciplinary communication.	3	2	2	2	3	2.4
	CO5	Demonstrate teamwork, leadership, and negotiation skills in group activities, discussions, and project settings.	2	2	2	3	2	2.2
	CO6	Critically evaluate the role of communication in patient	3	3	3	3	3	3.0
		Average	2.8	2.5	2.7	2.8	2.8	2.7
Research Project / Dissertation MCR 116	CO1	Formulate a research problem by reviewing scientific literature and identifying knowledge gaps in field of clinical research.	3	3	2	3	2	2.6
	CO2	Design and execute research projects using appropriate methodologies, tools, and techniques relevant to biomedical research.	3	3	3	3	3	3.0
	CO3	Demonstrate proficiency in designing ,handling & conducting advanced research project including clinical trials	3	3	3	3	3	3.0
	CO4	Critically analyze and interpret experimental data using appropriate statistical and computational tools.	3	3	2	3	3	2.8
	CO5	Adhere to ethical standards in biomedical research, including biosafety, data integrity, and responsible reporting.	2	2	1	1	3	1.8
	CO6	Communicate research findings effectively through well-structured dissertation writing, presentations, and potential publications.	2	2	1	2	2	
	CO7	Work independently and collaboratively to solve research challenges and manage time efficiently during the project.	1	3	3	2	3	2.4
	CO8	Develop a research-oriented mindset that prepares them for higher studies, industrial R&D, or academic research careers	3	3	3	3	3	3.0
		Average	2.5	2.75	2.25	2.5	2.75	2.6
Internship/Training (Clinical/ Industrial) MCR 123 P	CO1	Apply theoretical knowledge of clinical research design, pharmacovigilance, and regulatory frameworks to real-world clinical or industrial settings, demonstrating practical competency and ethical conduct.	3	3	3	3	3	3.0
	CO2	Develop proficiency in clinical documentation and data management, including source data verification, CRF entry, query resolution, and adherence to GCP and SOPs during project execution.	3	3	3	3	3	3.0
	CO3	Demonstrate effective professional communication, teamwork, and coordination with multidisciplinary teams including investigators, monitors, regulatory personnel, and data managers.	3	2	3	3	3	2.8

	CO4	Analyze and interpret clinical, safety, and operational data to support evidence-based decision-making and contribute to ongoing or completed clinical studies, pharmacovigilance activities, or regulatory submissions.	3	2	2	2	3	2.4
	CO5	Reflect critically on the industrial/clinical work experience, identifying areas for skill enhancement, understanding organizational workflows, and integrating ethical, regulatory, and quality perspectives into professional practice.	2	2	2	3	2	2.2
		Average	2.8	2.4	2.6	2.8	2.8	2.7