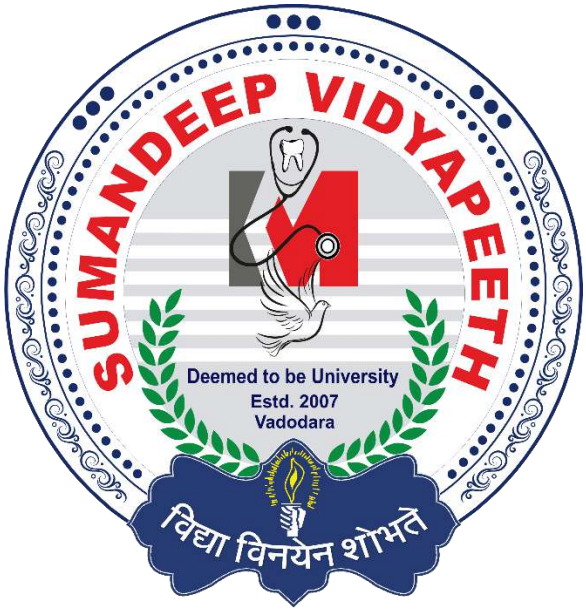

CURRICULUM

MSc Clinical Research

Sumandeep Vidyapeeth

An Institution Deemed to be University under Section 3 of UGC Act, 1956

At Post -Pipariya, Taluka - Waghodiya, District - Vadodara, Gujarat State, India.

Pin code - 391760.

CHAPTER –I

Eligibility Criteria for Admission

1.1 MSc in Clinical Research:

Applicants must hold a degree in B. Pharm, Pharm D, M. Pharm, MBBS, BDS, BAMS, BHMS, BPT, BSc Life Sciences, or an equivalent qualification. Candidates who are awaiting the results of their final year exams are also eligible to apply.

1.2 Program Duration

The MSc in Clinical Research is a two-year program, structured across four semesters.

1.3 Language of Instruction and Examination

All instruction and examinations will be conducted in English.

1.4 Academic Calendar

Each semester will comprise a minimum of 100 working days. The first semester typically runs from July/August to December/January, and the second semester from January/February to June/July annually.

1.5 Attendance and Academic Progress

Students must maintain a minimum of 75% attendance in each course, with theory and practical components evaluated separately. Completion of all prescribed course is mandatory to qualify for the corresponding examinations.

1.6 Curriculum Structure

The MSc Clinical Research curriculum includes both theoretical and practical components, organized semester-wise as detailed in Tables I–IV. The allocated instructional hours for each theory and tutorial course in a given semester will be no less than what is specified in the respective tables.

Scheme and Syllabus

Table -1 (I-Semester)

Course Code	Course Title	Teaching/week (hr.)			Mark Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR-101T	General Pharmacology – 101	3	-	-	30	70	100	3	3
CR-102T	Fundamental of Anatomy, Physiology, Pathophysiology	3	-	-	30	70	100	3	3
CR-103T	General Epidemiology and Disease Epidemiology	3	1	-	30	70	100	3	4
CR-104T	Pharmacotherapeutics	3	1	-	30	70	100	3	4
					120	280	400	--	14

Table -2 (II-Semester)

Course Code	Course Title	Teaching/week (hr.)			Mark Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR-201T	Drug Discovery & Clinical Research	3	-	-	30	70	100	3	3
CR-202T	Regulation & Guideline in Clinical Research	3	1	-	30	70	100	3	4
CR-203T	Basics of Biostatistics	3	-	-	30	70	100	3	3
CR-204T	Clinical Research Documentation	3	1	-	30	70	100	3	4
CR-205P	Clinical Research Documents-I	-	-	4	30	70	100	3	4
					150	350	500	--	18

Table No. 3- (III- Semester)

Course Code	Course Title	Teaching/week (hr.)			Mark Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR-301T	Clinical Trial Operation Management	3	-	-	30	70	100	3	3
CR-302T	Bioavailability / Bioequivalence (BA/BE) studies	3	-	-	30	70	100	3	3
CR-303T	Clinical Trial Data Management	3	1	-	30	70	100	3	4
CR-304T	Pharmacovigilance & Post Marketing Surveillance	3	1	-	30	70	100	3	4
CR-305P	Clinical Research Documents-II	-	-	4	30	70	100	3	4
					150	350	500	--	18

Table No. 4- (IV-Semester)

Course Code	Course Title	Teaching/week (hr.)			Mark Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR-401	Dissertation (Project work)	-	6	-	100	100	200	-	3

1.7 Examinations and Assessments

For each theory and practical course in Semesters I to III, students must appear in sessional exam of one hour worth 30 marks, scheduled by the institute. In addition, end-semester examination of three hours conducted by the university will carry a weightage of 70 marks per course.

1.8 Dissertation (Project work)

During Semester IV, students must undertake a dissertation project. Evaluation of the dissertation will be based on both a formal presentation and a viva-voce (oral examination).

1.9 Overall Assessment

The final assessment will comprise a combination of the project presentation and the viva-voce.

1.10 Examination/Assessments

The scheme for internal assessment and end semester examinations is given in Table No. 5.

Table -5: Schemes for internal assessments and end semester examinations semester-wise.

Semester-I

Course code	Name of course	Internal Assessment				End semester		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
CR-101T	General Pharmacology	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-102T	Fundamental of Anatomy, Physiology, Pathophysiology	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-103T	General Epidemiology and Disease Epidemiology	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-104T	Pharmacotherapeutics	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**

Semester-II

Course code	Name of course	Internal Assessment				End semester		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
CR-201T	Drug Discovery & Clinical Research	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-202T	Regulation & Guideline in Clinical Research	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-203T	Basics of Biostatistics	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-204T	Clinical Research Documentation	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-205P	Clinical Research Documents-I	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**

Semester-III

Course code	Name of course	Internal Assessment				End semester		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
CR-301T	Clinical Trial Operation Management	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-302T	Bioavailability / Bioequivalence (BA/BE) studies	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-303T	Clinical Trial Data Management	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-304T	Pharmacovigilance & Post Marketing Surveillance	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**
CR-305P	Clinical Research Documents-II	**10**	**20**	**1 hr**	**30**	**70**	**3 hrs**	**100**

Semester-IV

Course code	Name of course	Internal Assessment			External Assessment	Total
		Continuous mode	Viva-voce	Total		
CR-401	Dissertation (Project work)	**50**	**50**	**100**	**100**	**200**

SYLLABUS

SEMESTER-I

CR-101 - General Pharmacology 3hrs/week

- **General Pharmacology-:** Introduction, scope and branches of pharmacology, sources of drugs and nomenclature of drugs, dosage forms, Routes of drugs administration and drug delivery systems, factors modifying drug action, tolerance and dependence, dynamics of absorption, distribution and excretion of drugs, Basic pharmacokinetic parameters employed in the use of drugs, their bioavailability and biotransformations, metabolizing enzymes as targets of drugs action- enzyme induction and inhibition, biological half-life and its significance, Models of pharmacokinetics, Pharmacodynamics-mechanism of drug action, site of drug action, drug receptor interaction types of receptors, Bioavailability and Bioequivalence, Drug antagonism and synergism, dose response relationship, drug dependence, Adverse drug effects and their monitoring, Iatrogenic diseases, Pharmacogenomics, pharmacoeconomics
- **Overview of Drug Pharmacology:** Current interventions, classification of drugs, pharmacokinetics, therapeutic effects, mechanism of action, adverse effects and contraindications, dose, marketed preparations of the following class ofdrugs
- **Drugs acting Central Nervous System(CNS):** Autonomic and somatic transmission, General anesthetics, anxiolytics and hypnotics drugs, anti depressants, CNS stimulants and psychotomimetic drugs, Opioid analgesics and opioid anatagonists, Drug dependence and drug abuse, Antiepileptic drugs, Drug therapy for neurodegenerative disorders like parkinson's disease and schizophrenia
- **Drugs acting on Autonomic Nervous System (ANS)**: General introduction, Parasympathomimetic, parasympatholytic, Sympathomimetic, sympatholytic agents, Ganglionic stimulants, blockers and adrenergic neuron blocking drugs, local anesthetics
- **Drugs acting on Cardiovascular System (CVS)**: Cardiac glycosides and positive ionotropic agents, Anti-arrhythmic drugs, Antihypertensive drugs, Coronary vasodilators and drugs used in angina, Anti-hyperlipidemic drugs, Fibrinolytic agents, Cardioprotective agents,
- **Antihypertensives**: Overview, classification of antihypertensive drugs- Diuretics, Sympatholytics, angiotensin inhibitors, vasodilator, dopamine agonists
- **Drugs acting on Respiratory System**: Expectorants, Anti-tussive bronchodilators, Drugs used in common cold

- **Anti Cancer:** Types of cancer, etiology of Cancer , drugs used in cancer chemotherapy, toxicities of drugs used in cancer chemotherapy, resistance to cytotoxic drugs, Preferred combination chemotherapy for certain malignancies
- **Anti Diabetic:** Insulin preparation, types of diabetes, Antidiabetic drugs: Sulfonylurea drugs, Meglitinide drugs, Alpha-glucosidase inhibitors, Biguanide, thiazolodinediones
- **Non Steroidal Anti-Inflammatory Drugs(NSAIDS):** Classification of NSAIDS, Mechanism of action , NSAIDSwhich do not inhibit prostaglandin synthesis
- **Anti-Coagulants, Antiplatelet and Fibrinolytic Drug:** Normal hemostatis, anticoagulant drugs, parenteral anticoagulants, antiplatelet drugs, fibrinolytic drugs
- **Chemotherapy of Microbial Diseases:** Introduction to chemotherapy, Sulfonamides, Qinolones and treatments of urinary tract infection, Penicilins, cephalosporins and other β- lactum antibiotics, Aminoglycosides, Microlides, other antibacterial drugs, broad spectrum antibiotics: Tetracyclines and chloramphenicol, Chemotherapy of tuberculosis and leprosy

CR-102- Fundamental of Anatomy, Physiology, Pathophysiology

3hrs/week

- **Basics of Anatomy & Physiology:** Cells, tissues, structure and functions
- **Blood**: Plasma, erythrocytes, hemoglobin and anemia, leucocytes, thrombocytes, coagulation of blood, blood groups and transfusion, immunity, tissue macrophage system and lymph
- **Nerve**: Nerve biophysics, Neuron, Nerve conduction and classification of nerve fibers
- **Muscle**: Skeletal muscle structure and mechanism of contraction, Mechanism of muscle contraction, Neuromuscular transmission
- **Cardiovascular System**: Anatomy of the heart, Circulatory system including Arterial and Venous system with special reference to the names and positions of main arteries and veins, Properties of Cardiac muscle, Blood pressure and its regulation, Renin Angiotensin system and its significance, Physiology of cardiac muscle, cardiac impulse, electrocardiogram, cardiac cycle, heart sounds, heart rate and its regulation, cardiac output, arterial pulse and venous pulse, cardiovascular changes in muscular exercise, circulatory shock, cardiac failure
- **Respiratory System**: Anatomy of Respiratory organs, Functional anatomy of respiratory system, mechanics of respiration, lung volumes and capacities, dead space, alveolar ventilation and diffusion of gases, parameters like VC, TC, FEV, transport of oxygen, transport of carbon dioxide, regulation ofrespiration, artificial respiration
- **Excretory System and Body Fluids**: Various parts of urinary system and their functions, Structure and functions of Nephron, formation of urine, micturition, renal function tests, electrolyte balance, juxtaglomerualr apparatus, body fluids, skin and body temperature, metabolic function of liver, gall bladder and related glands, mechanisms of excretion
- **Endocrine Glands and Reproduction**: Role of Endocrine Glands in Regulation and Integration of various functions of the Body, Anatomy and Physiology, General considerations, pituitary gland, thyroid gland, endocrine regulation of calcium and phosphorus metabolism, parathyroid gland, islets of langerhans, adrenal gland, prostaglandins, thymus and pineal gland, female reproductive system, male reproductive system
- **Nervous System**: Divisions of Nervous System, Central Nervous System (Brain &

Spinal Cord), Reflex action, Electroencephalogram (EEG), Overview of Neurotransmitters, Peripheral Nervous System (PNS) (Cranial nerves & spinal nerves)Synaptic transmission, sensory receptors, pain, reflex action, spinal cord, thalamus, cerebellum, cerebral cortex, Sleep, hypothalamus, cerebrospinal fluid, autonomic nervous system

- **Digestive System**: Organization of digestive tract, digestive secretions, gastrointestinal hormones, liver, gastrointestinal motility, absorption of food
- **Special Senses:** Vision, hearing, chemical senses
- **Fundamentals of Pathophysiology:** Derangement of Homeostasis and hemodynamics, Definition, terminology, pathology of following diseases including etiology, risk factors, signs and symptoms, overview of treatment and diagnosis of the disease
- **Diseases-** Systemic pathology of blood vessels and lymphatics, liver, exocrine pancreas, kidney, endocrine system, musculoskeletal system, nervous system, system associated diseases like Hypertension, congestive heart failure, cardiac arrhythmias, ischemic heart diseases, obesity, atherosclerosis, bronchial asthma, chronic pulmonary obstructive disease, tuberculosis, peptic ulcer disease, inflammatory bowel disease, HIV infection and AIDS, hepatitis, anemia, Type 1 and type 2 diabetes, cancer and its types, rheumatoid arthritis, schizophrenia, depression, migraine, anxiety, insomnia, normal ranges of laboratory parameters.

CR-103- General Epidemiology and Disease Epidemiology

3hrs/week

- **General Epidemiology**
  Definition: Epidemiology,
  Disease distribution, disease determination, disease frequency, Aim of epidemiology, Difference between epidemiology and clinical medicines, Epidemiological approach, Measurements in epidemiology, (rates, ratios, and proportions)

- **Measurement of mortality**: international death certificate, limitations and use of mortality data, mortality rates and ratios, crude death rates, specific death rates, case fatality ratio, proportional mortality ratio, survival rate, standardize rates, direct standardization, indirect standardization,
- **Measurement of morbidity**: Incidence, Prevalence, uses of prevalence, relationship between incidence and prevalence,

- **Epidemiological methods**:

  a) **Descriptive epidemiology**

  - **Time distributions**
    - Short term fluctuations: Types of Epidemics- single exposure/point source exposure epidemics, continuous exposure epidemics, propagated epidemics, slow epidemics
    - Periodic fluctuations
    - Long term fluctuations
  - **Place Distributions**
    - International variance, National variance, Rural-Urban variations, Local distributions. Person distributions:

  b) **Analytical epidemiology**

  - **Case control study**
    Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study., advantages, disadvantages and some examples of case control study

  - **Cohort study**
    Concept, framework, prospective and retrospective cohort study, combination of prospective and retrospective cohort study, elements of cohort study, relative risk, attributable risk, advantages, disadvantages and examples of cohort study.

c) <u>Experimental epidemiology:</u>

Randomized controlled trials: Protocol, selecting reference and populations, randomization, manipulation, follow-ups, assessment, study designs in randomized trials like parallel and cross over study, Types of randomized controlled trials: clinical trial, preventive trials, risk factor trials, cessational trials, trial of aeitiological agents,

Non-randomized trials: uncontrolled trials, natural experiments, before and after comparison studies

Ethical principles in pre-clinical studies and clinical trials, History, its Principles

Roles & Responsibility of various clinical trial personnel as per ICH GCP and ICMR guidelines like Sponsor, Investigator, Monitor, Auditors

CR-104- Pharmacotherapeutics

3hrs/week

- **Pharmacotherapy of Disease Associated with Following Systems.**
    - **a. Cardiovascular:** Hypertension, Congestive Cardiac Failure, Ischemic Heart Disease, Myocardial Infarction, Arrhythmias, and Hyperlipidemias.
    - **b. Respiratory System:** Asthma, Chronic Obstructive Airway Disease
    - **c. Haematological Disease:** Anemia, Deep Vein Thrombosis
    - **d. Rheumatic Disease:** Rheumatoid Arthritis, Osteoarthritis, Systemic Lupus Erythematous.
    - **e. Gastrointestinal System:** Peptic Ulcer Disease, Reflux, Oesophagitis, Inflammatory Bowel Disease, Hepatitis & Cirrhosis.
    - **f. Skin and Sexually Transmitted Disease:** Psoriasis, Syphilis, Gonorrhea, Drug Related Skin Reactions.
    - **g. Pain Management:** Drug used in management of pain, Neuralgias including post herpetic, trigeminal and glossopharyngeal neuralgia.
    - **h. Renal System:** Acute Renal Failure, Chronic Renal Failure
    - **i. Endocrine System:** Diabetes, Thyroid Disease, Hormone Replacement Therapy, Osteoporosis.
    - **j. Nervous System:** Epilepsy, Parkinson's Disease, Stroke
    - **k. Psychiatric Disorders:** Schizophrenia, Depression, Anxiety Disorder
    - **l. Infectious Disease:** General Guideline for the rational use of antibiotics, Meningitis, Pneumonia, Gastroenteritis, Septicemia, Urinary Tract Infection, Tuberculosis, Malaria, HIV & opportunistic infection, Fungal Infections.
    - **m. Oncology:** General principle of cancer chemotherapy, commonly used cytotoxic drugs, management of chemotherapy induced nausea and vomiting.

SYLLABUS

SEMESTER-II

CR-201- Drug Discovery & Clinical Research

3hrs/week

- **Drug Discovery**: Drug design-Ligand ba**se**d, Structure based, Active site identification, rational drug discovery High throughput screening, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD)
- **Phases in Clinical Development of Drug** : Terminology in clinical research, Preclinical phases, First in human trials, Single ascending dose and multiple ascending dose studies, Exploratory clinical trials, Confirmatory clinical trials, post marketing surveillance
- **Preclinical Study Guidelines** : Non clinical overview and non-clinical summaries(M4S(R2)), Non clinical safety studies(M3(R1)), Guidance on non-clinical safety studies for the conduct of Human clinical trials and marketing authorization, Dose response information to support drug registration(E4), Clinical safety data management, guideline on the need of carcinogenicity studies of pharmaceuticals(S1A), Duration of chronic toxicity testing in animals (rodent and non-rodent toxicity testing (S4), safety pharmacology studies for human pharmaceuticals (S7A), Non clinical evaluation for anti-cancer pharmaceuticals (S9)
- **History & Background of Origin of Clinical Research:** Thalidomide tragedy, Sulphanilamide disaster, WMA Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects, The Belmont Report
- **Types of trials:** Pharmacoepidemiology, Meta-analysis, Case control study, Prevention Trials, diagnostic trial, Treatment trial, Case cohort study, Observational studies, Quality of life trials
- **Fundamentals of Trial Design –** Randomized clinical trial, uncontrolled trials, protocol development, end points, Patient selection, sources and control of bias, Randomization, sample size and power
- **Clinical/Contract Research Organizations(CRO)** - Definition, fundamental operations of CRO, Role and responsibilities of CRO, Organogram of CRO, basic documentation in CRO, Site Management Organizations (SMO), Central Lab, Research Management Organizations and differences between Contract Research

Organization/Site Management Organization/Research Management Organization, Functions of Quality Assurance and Quality Control Departments, Bioanalytical Departments, Clinical Project Management, Regulatory affairs, Medical Writing and Data Management, Biostatistics

- **Study Execution Process-** Study design, Feasibility, Overview of National regulatory applications, CR professional training and development, preparations and planning for clinical trials, CRF and monitoring, Training and site management**,** Budget Management of Clinical trials\

CR-202- Regulation & Guideline in Clinical Research

3hrs/week

- **Ethical Aspects:** Ethical principles underlined research involving human subjects, respect for persons, beneficence, justice, legal authorities for Institutional Review Board (IRB), Health and Human Services regulations(HHS) , FDA regulations, regulatory requirements, duties of IRBs, IRB membership, role of IRB in reviewing Clinical Drug Trials, Assessment of scientific design, competence of investigator, selection of subjects, balancing benefits and risks , Compensation for research related injuries, special issues like role of Lay member of IRB, review of multi institutional trials, duty to monitor, financial risks of clinical trial subject, compliance with new regulations
- **History of Good Clinical Practices (GCP):** Introduction to ICH-International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP , The Nuremberg Code, Principles of ICH-GCP
- **Applicable GCP Guidelines:** International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP), Indian Council Of Medical Research- Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices
- **International Regulatory bodies and Guidelines**:
  - ***US Food and Drug Administration(USFDA):*** The FDA and Food Drug and Cosmetics Act, New drug development and approval : the principal steps
  - ***India:*** Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices
  - ***Medicines and Healthcare Products Regulatory Agency (MHRA)***: Overview of regulatory environment/ background, regulatory authorities, regulatory requirements and procedures
  - ***European Agency for Evaluation of medicinal Products(EMEA)***: National registration , the decentralized procedures, mutual recognition procedures
  - ***Brazil*:** Overview of regulatory affairs
- **Good Laboratory practices(GLP) :** Organization and Personnel, Quality assurance program, Facilities, Equipments, reagents and Materials, Standard operating procedures, Storage of Records and Reports

- **Council for International Organizations of Medical Science (CIOMS) guidelines:** CIOMS International Ethical guidelines for biomedical research involving human subjects, Principles Of Medical Ethics Relevant To The Protection Of Prisoners Against Torture (1983)
- **Intellectual Property Rights:** Terminology, Patent Laws, TRIPS (Trade Related Intellectual Property Rights) Agreement, Trademarks, copyrights
- **Clinical Trial Application Requirements**
    - **Investigational New drug (IND):** Classifications, IND application submission check list, FDA IND review check list , IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions
    - **New Drug Application(NDA)**: Pre NDA meeting , NDA submission Check list , FDA NDA review check list
    - **Abbreviated New drug Application(ANDA):** ANDA content, ANDA Submission check list , FDA ANDA review check list , ANDA process for generic drugs, guidance documents for ANDAs, ANDA forms and electronic submissions
- **Orphan Drugs Application :** Submission check list, FDA orphan drug review check list , FDA documents

CR-203- Basics of Biostatistics

3hrs/week

- **Introduction to Biostatistics & its role in Clinical Research:** Population & Sample, Parameter & Statistic, Types of variables, Measures of Central Tendency-Mean, different types of mean, Median, Mode, Histograms, Scatter Plots, Construction & Labeling of graphs, Normal & Binomial Distribution, Research Hypothesis testing, Sample size calculation & Power, p-value, Confidence Interval, Randomization methods, Blinding in Clinical research

- **Probability:** Definition and Application

- **Parametric Tests:** Definition and Application
  Analysis of variance-One Way and Two Way
  a) McNemar's test
  b) Exact probability test

- **Rank score tests –** Definition and Application
  a) Wilcoxon signed rank test,
  b) Wilcoxon two sample rank test,
  c) The Mann Whitney Test,
  d) The Spearman Test,
  e) The Friedman Test.

- F-test – testing of two population variances

- Study design and choosing a statistical test Design-Assignments

CR-204- Clinical Research Documentation

3hrs/week

- **Clinical Trial Documentation:**
  - **Investigator's Brochure**- Confidentiality Statement, Summary, Introduction, Physical, Chemical, and Pharmaceutical Properties and Formulation, Nonclinical Studies, Nonclinical Pharmacology, Pharmacokinetics and Product Metabolism in Animals, Toxicology, Effects in Humans, Pharmacokinetics and Product Metabolism in Humans, Safety and Efficacy, Marketing Experience, Summary of Data and Guidance for the Investigator
  - **Study Protocol -** The contents of a trial protocol should generally include the topics: General Information, Background Information, Trial Objectives and Purpose. Trial Design, Selection and Withdrawal of Subjects, Treatment of Subjects, Assessment of Efficacy, Assessment of Safety, Biostatistics, Direct Access to Source Data/Documents, Quality Control and Quality Assurance, Ethics, Data Handling and Record Keeping, Financing and Insurance, Publication Policy, Supplements, Annexure
  - **Case Report Forms (CRF) & e-CRF-** Study Title, Inclusion Criteria, Exclusion Criteria, Patient Screening, Admission /discharge procedure, Visit wise, Period wise, Laboratory Analysis, Vital signs, Diet restriction, Concomitant medication, withdrawal/drop out details, Adverse Events Form, Serious Adverse Event Form
  - **Informed Consent Form/Assent Form-** Study title, What is the purpose of research, The study design, Study Procedures, Women of childbearing potential, Possible risks , Possible benefits, Compensation, Possible benefits to other people, The alternatives you have, Cost to the participant, Confidentiality of the information of subject/patient, decision to participate/ not participate, Withdrawal of the consent, Right to new information, Contact persons, Patient consent form, Patient Information Sheet, Patient visit diary
  - **Clinical Study Report**- Title Page, Synopsis, List Of Abbreviations And Definitions Of Terms, Ethics, Investigators And Study Administrative Structure, Introduction, Study Objectives, Investigational Plan, Study Patients, Efficacy Evaluation, Efficacy Evaluation, Discussion And Overall Conclusions, Tables, Figures and Graphs Referred, Reference List, Appendices
- **Standard Operating Procedures (SOP) in Clinical Trials** - Need of SOPs, What is SOPs, Benefits of SOPs, different types of SOPs, SOP Writing SOPs and Guideline, Implementation and monitoring of SOPs, Change control
- **Essential Documents-**Importance of Essential Documents

- **Pre Study Document**: Investigators Brochure, Financial aspects of the trial, Approval letter from the IRB, IRB Composition etc
- **During the Study Documents**: Updates on medical/laboratory/technical procedure tests, Investigational product(s) accountability at site, Subject enrolling log, Audit certificate etc
- **Post Study Documents**: Final report by investigator to IRB, Final report by investigator to regulatory authorities, Clinical study report to document results and interpretation etc, Study Completion documents, Study Termination/closure documents

- **Procedures in Clinical Trial**
  - **Quality Assurance and Quality Control in Clinical Research** –Introduction, Regulatory requirement of quality Assurance(QA) and Quality Control (QC) in Clinical Research, Role and Responsibilities of QA personnel, Different types of Audit, Quality System and Quality Policy, Continual Process Improvement
  - **Interventions, Study Drug Packaging and Distribution** Study Drug Receipt, Dispensing, Accountability, Storage, Disposal, Regulatory Requirement. An over view of clinical trial interventions, describe issues related to study drug packaging and masking, discuss logistics of study drug distribution, and describe treatment adherence in clinical trial
  - **Monitoring in Clinical Trials**: Purpose of monitoring & Monitor's responsibilities, Selection and qualification of monitors, Monitoring procedures, Monitoring report, Audit, Extent and nature of monitoring , Medical Monitoring, Query Resolution
  - **Project Management and Business Development:** Skills of Business Development personnel, Roles and responsibilities of a Project manager, Project Management matrix, Business development strategies.

CR-205P

Clinical Research Documents-I

4 hrs/week

- **Preparation of Protocol:**

Rationale, objectives, methodology, statistical considerations, and organizational structure of a clinical study.
Key components covered: Title Page: Includes trial title, protocol number, version/date, sponsor details.

Background and Rationale: Scientific justification and existing data.

Objectives and Endpoints: Primary, secondary, exploratory objectives and measurable outcomes.

Study Design: Description of type (RCT, cohort, observational), blinding, randomization.

Study Population: Inclusion/exclusion criteria, recruitment strategy.

Investigational Product Details: Dosage, administration, storage, accountability.

Assessments and Visits Schedule: Study procedures, laboratory tests, imaging, and timelines.

Adverse Event Monitoring and Reporting: Definitions, timelines, reporting flow.

Statistical Analysis Plan: Sample size, statistical methods, interim analysis.

Ethical and Regulatory Considerations: EC approval, informed consent, protocol amendments.

Confidentiality and Data Handling: Subject privacy and data integrity protocols.

- **Preparation of Various Standard Operating Procedures (SOPs) in Clinical Research**

Definition and Purpose of SOPs, Hierarchy of SOP Documentation

Format and Template Structure: SOP title, version control, objective, scope, responsibilities, procedures, and annexures.

Types of SOPs in Clinical Trials: Informed Consent Process SOP, Site Qualification and Site Initiation SOP, Adverse Event Reporting SOP, Clinical Trial Monitoring SOP, Source Document Archiving SOP, SOP for Protocol Deviation Handling.

Process of SOP Development: Drafting, review, training, approval, implementation.

Change Control and Versioning, Auditing and SOP Compliance

- **Preparation of Investigator Brochure (IB)**

Definition and objectives

IB Content includes: Product Overview and Chemical Properties

Pharmacological Profile: Pharmacodynamics and pharmacokinetics.

Toxicology Data: Animal study data and safety margins.

Clinical Data Summary: Prior human studies (if any), efficacy signals, AEs observed.

Safety Monitoring Guidelines: Contraindications, precautions, interactions.

Dosage and Administration Guidance, Structure and Format as per ICH E6(R3)

- **Preparation of Regulatory Documents**

Key documents required to initiate and conduct clinical trials from a regulatory standpoint:

A. Investigator Undertaking (As per NDCT 2019 India):

PI's commitment to conduct the trial ethically and scientifically.

Compliance with GCP, protocol, and regulatory requirements.

Declaration of conflict of interest.

B. USFDA Forms:

Form 1572: Statement of Investigator – required for IND trials in the U.S.

Financial Disclosure Forms: 3454 and 3455 – to disclose any financial interest of the investigator. IND/IDE Application Support Documents, Regulatory document maintenance and version control.

- **Preparation and Reporting of Serious Adverse Event (SAE) Forms**

Handling and reporting adverse events during clinical trials, with a focus on SAE documentation and compliance:

Key topics:
Definition of SAE as per ICH and NDCT 2019, 24-hour Reporting Rule in India (DCGI requirement),

Components of SAE Form:

Patient demographic details, Description of event, Timeline, Outcome, Causality assessment by investigator, SAE Narrative Writing, Role of Data Safety Monitoring Board (DSMB), Compensation and Medical Management Records, Submission timelines to Ethics Committee and Regulatory Authority

- **Handling of SUGAM Portal**

About Online submission system developed by the Central Drugs Standard Control Organization (CDSCO), India, for regulatory submissions.

Training includes:

User Registration and Role Allocation

Module Navigation: Clinical trial module, ethics committee module, medical device module, etc.

Submission of Form CT-04, CT-06, CT-10, etc., uploading documents and checking status, Communication with CDSCO, Common issues and error resolutions, Digital Signature Certificate (DSC) Management, Post-approval submission and updates

SYLLABUS

SEMESTER-III

CR-301- Clinical Trial Operation Management

3hrs/week

- **Operation in CRO & SMO**
    - **Site Selection Criteria**- Site Selection parameters: Location, Staffing, Qualifications, History, Clinical trial experience, Area of therapeutic experience, Investigational pharmacy, ICH-GCP compliance, Patient enrollment, Site Selection Check list, Site Initiation Visit (SIV)
    - **Single Centre/Multi Centre Trial**- Definition, benefits of Single center and or Multi center, Differences between Single center & Multi-center Trial
    - **Investigator Selection**

      Investigator qualification and agreement, duties delegation, Undertaking by the Investigator, Feasibility study, Other functions-Central lab, Shipment and shipping records, meetings with Sponsor, analysis & interpretation of results etc.
- **Operation of Institutional Review Board (IRB)/ Independent Ethics Committee (IEC)** - Defining Scope of IRB/IEC Authority**,** Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with IRB, IRB/IEC Records, Documents for submission to IRB/IEC, Difference between IRB and IEC
- **Roles & Responsibilities of Clinical Trial Personnel**
    - Roles & Responsibilities of Sponsor
    - Roles & Responsibilities of Investigator
    - Roles & Responsibilities of CROs/SMOs
    - Roles & Responsibilities of CRA/Monitor
    - Roles & Responsibilities of Auditor
    - Roles & Responsibilities of Clinical Research Coordinator
    - Roles & Responsibilities of Clinical Data Manager
    - Roles & Responsibilities of Clinical Biostatistician

CR-302- Bioavailability / Bioequivalence (BA/BE) studies

3hrs/week

- **Introduction to Bioavailability & Bioequivalence**- Basic Definitions, Requirements of Bioavailability and Bioequivalence study, Study Design, Bio statistical procedure, Bio analytical method and Method validation, submission of study to the regulatory, Bioequivalence and Pharmacokinetics
- **Guidelines of Bioavailability (BA)/ Bioequivalence (BE) Studies**
  - **USFDA guideline**- Introduction, Background, Methods to document BA and BE, Comparison of BA measures in BE studies, Documentation of BA and BE, Special topics, General pharmacokinetic study design and data handling
  - **ANVISA guideline**- Introduction, Background, Acceptance Criteria of BA/BE Unit, General Consideration for BA/BE study, Guidance for Protocol Design of BA/BE study, Guidance for report preparation of BA/BE study
  - **Overview of International BABE guidelines:** Therapeutic Goods Administration **(**TGA) guideline, Therapeutic Product Directorate **(**TPD) guideline, European Agency for Evaluation of medicinal Products (EMEA) guideline
- **Regulatory Submissions**: Drugs Controller General of India (DCGI)/Central Drugs Standard Control Organization (CDSCO) submissions, Directorate General of Foreign Trade (DGFT), T-License, e-CTD (Common Technical Document)
- **Difference in various Bioavailability (BA)/ Bioequivalence (BE) Guidelines**- Different Regulatory Bodies and differences in terms of: Selection of Reference Product, Drug content / potency, Number of subjects, Inclusion Criteria, Exclusion Criteria, Dosing Water Quantity. Water restriction and food restriction, requirement of Fed Study, Minimum sample points, Length of blood sampling time, Washout, Metabolites concentration measurement, Drugs with non-linear Pharmacokinetic, Drugs with Long Half-life, Modifies release formulation, Withdrawal /dropout criteria, Outliers, Retention period for Study Drugs sample
- **Conduct of Bioequivalence study**- Role of Different Departments involve in Bioequivalence study (Business development, Screening department, Clinical department, Bio-analytical department etc), Life span of Bioavailability and Bioequivalence study(BABE study), day to day activity during the study
- **Operations in BABE**: Role of Quality Assurance & Quality Control in BA/BE studies, Role of Medical Writing in BA/BE studies, Waiver of BA/BE Studies, Role of Project Management and Business development in BA/BE studies

CR-303- Clinical Trial Data Management

3hrs/week

- **Introduction to Clinical Data Management(CDM):** Definition, Steps in CDM, Data management process and work flow, Code of Ethics for CDM professionals **,** CDM and case record form (CRF), needs of CRF users, standardization of CRFs, guidelines for designing CRF
    - **Data Entry/Remote data entry**: First data entry, Second data entry, heads up and heads down data entry, audit trail, 21CFR part 11, computerized system in clinical trials, QAQC in data entry
    - **Data Tracking**: Tracking CRF pages and corrections, CRF work flow, tracking challenges, tracking of query forms
    - **Data Capture:** Definition, paper based and electronic data capture, dataflow in paper CRFs and e-CRFs, tools for data capture, advantages and disadvantages of paper CRF/ e-CRF
    - **Data Coding**: Definition, data quality, coding significance, coding dictionaries, Coding symbols for a thesaurus of adverse reaction terms (COSTART), problems with Coding data, special search categories, coding of AE data
    - **Data cleaning/validation**: Definition, Discrepancy management system, edit check specifications, query management, cleaning data checklist, SAE reconciliation, managing laboratory data, data locking/freezing
    - Overview of Data management Software(s)

CR-304- Pharmacovigilance & Post Marketing Surveillance

3hrs/week

- **General overview of Pharmacovigilance:** Introduction, Definitions**,** Adverse Event (AE), Adverse Drug Reaction(ADR), Serious Adverse Drug Reaction (SAE), Unexpected Adverse Reaction, Suspected unaccepted serious Adverse reaction (SUSAR), Signal and Detection of Signal, Diagnosis and management of adverse drug reactions, Periodic safety Update Report(PSUR), Individual case safety report, Spontaneous reporting, Risk Evaluation and Mitigation Strategy, Significance of Pharmacovigilance, Audit in Pharmacovigilance
- **Pharmacovigilance and ICH guideline:** ICH-E2A Clinical Safety Data Management – Definitions and Standards for Expedited Reporting, ICH-E2C Clinical Safety Data Management – Periodic Safety Update Reports for Marketed Drugs,ICH-E2D Post-Approval Safety Management – Definitions and Standards for Expedited Reporting, ICH- E2E Pharmacovigilance Planning
- **Pharmacovigilance regulations and guidelines**: Role of Pharmacovigilance in Drug Regulation, Regulatory aspects in Pharmacovigilance, European Union PV guidelines, Australian PV guidelines, Good Pharmacovigilance practices (GPP), Expedited reporting requirements
- **Pharmacovigilance in India:** Pharmacovigilance centers in India, CDSCO Indian PV guidelines-National Pharmacovigilance Program (NPP)
- **Pharmacovigilance in Europe:** Guidelines for Marketing Authorization Holders (MAH), General Principles, Risk management plan(RMP), Contents of EU-RMP, Expedited Reports, Reporting in Special Situations, Periodic Safety Update Report (PSUR)
- **Adverse Event reporting form**: MEDWATCH, CDSCO Adverse Event Reporting Form, CIOMS form for Serious Adverse event reporting, Anonymised Single Patient reports (ASPR-MHRA), Medication errors reporting
- **Pharmacovigilance Dictionaries**: MedDRA (Medical Dictionary for Regulatory Activities), MedDRA structure and content, WHOART (WHO-Adverse Reaction Terminology), Eudravigilance, CO-START
- **Global Pharmacovigilance & safety standards**- Pharmacovigilance activity in USA, Australia, WHO Monitoring of safety aspects – Uppasla Monitoring Center

- **Periodic safety update reports(PSUR) for marketed drugs :** Brief Introduction and Purpose of Periodic safety Update Report, PSUR Content, PSUR Process, Various Regulatory Requirement for PSUR

CR-305P

Clinical Research Documents-II

4 hrs/week

- **Preparation of Case Record Form (CRF)**

Definition and objectives.

Detailed components include: Purpose and Importance of CRFs, Types of CRFs: Paper-based and Electronic CRFs (eCRFs)

Design Principles: Simplicity and logical flow, avoiding ambiguity, Capturing protocol endpoints and safety data

Sections of a CRF: Demographics, Informed Consent Verification, Inclusion/Exclusion Criteria, Medical History and Concomitant Medications, Study Visit Details, Laboratory and Diagnostic Test Results, Adverse Events and Concomitant Therapy, CRF Annotation and Guidelines (CDASH, SDTM standards), CRF Completion Guidelines and Query Management, Audit Trail and Data Traceability

Practical Component: Designing CRF for an interventional or observational clinical trial using real-world protocols.

- **Preparation of Various Standard Operating Procedures (SOPs) in Clinical Trial Data Management**

SOPs specific to Data Management activities that ensure the integrity, accuracy, and security of clinical trial data.

Key topics covered: Introduction to Clinical Data Management (CDM), Importance of SOPs in CDM.

SOPs commonly used in Data Management: Data Collection and Entry SOP, Database Design and Validation SOP, Query Management SOP, Data Cleaning and Discrepancy Resolution SOP, Medical Coding SOP (MedDRA, WHO-DD), Data Lock and Database Archival SOP, Structure and Template of SOPs, Version Control and SOP Maintenance Training and Implementation of SOPs.

Compliance with GCDMP (Good Clinical Data Management Practices)

Outcome: Students will develop, format, and maintain CDM SOPs with real-world documentation examples.

- **Preparation of Modules of Electronic Case Record Form (eCRF)**

Electronic CRFs (eCRFs) are web-based platforms that allow real-time data entry, monitoring, and validation. This section focuses on how eCRFs are structured, developed, and validated as part of Electronic Data Capture (EDC) systems.

Key modules include: Understanding eCRF Systems (e.g., Medrio, OpenClinica, REDCap, and Oracle InForm), Differences between Paper CRF and eCRF,

eCRF Module Design: Login and access control, Subject registration and visit schedule

Data input fields (dropdowns, radio buttons, validation checks), Integrated edit checks and real-time validations, Auto-calculation fields (e.g., BMI, scores), User Roles and Permissions (Investigator, CRA, Data Manager), Data Security and Regulatory Compliance (21 CFR Part 11), eCRF Validation and User Acceptance Testing (UAT), Audit Trail and System Logs, Mid-study changes and Change Control.

Practical Component: Hands-on demo of designing an eCRF module for a clinical trial using open-source or commercial tools.

- **Preparation of Regulatory Documents – Clinical Study Reports (CSRs)**

Definition, objectives and importance with reference to DCGI, USFDA and EMA.

Topics covered: ICH E3 Guidelines for CSR,

Structure of a CSR: Title Page and Signature Pages, Synopsis and Study Overview, Study Objectives and Investigational Plan, Subject Disposition, Protocol Deviations and Amendments, Efficacy Evaluation and Statistical Analysis, Safety Evaluation (Adverse Events, SAEs), Pharmacokinetics and Pharmacodynamics (if applicable), Discussion and Conclusions,

Annexures: Protocol and amendments, CRF examples, Audit certificates, Investigator CVs

Ethics Committee approvals,
Preparation of CSR for India-specific trials (NDCT 2019-compliant)

Submission Guidelines: DCGI, USFDA, EMA

Redaction and Data Transparency for Public Disclosure

Practical Component: Drafting a mock CSR synopsis and efficacy/safety data summary for a completed study.

SEMESTER-IV

CR-401- Dissertation (Project work)

Students will be posted at Department of Clinical Research, Dhiraj Hospital during their Project work to completer their dissertation.

1.11 Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of MSc Clinical Research program if he/she secures at least 50% marks in that particular course including internal assessment.

1.12 Carry forward of marks

In case a student fails to secure the minimum 50% in any theory or practical course as specified in (Table-5), then he/she shall reappear for the end semester examination of that course. However, his/her marks of the internal Assessment shall be carried over and he /she shall be entitled for grade obtained by him/her on passing.

1.13 Academic Progression

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not e eligible to carry his/her dissertation work until all the courses of I and II semesters are successfully completed**.**

1.14 Grading of performances

Letter grades and grade points allocations:

Based on the performance, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table- 6.

Table-6

Percentage of marks obtained	Letter Grade	Grade Point	Performance
90.00-100	O	10	Outstanding
80-89.99	A	9	Excellent
70-79.99	B	8	Good
60-69.99	C	7	Fair
50-59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

1.15 The Semester grade point average (SGPA)

The performance of a student in a semester is indicated b the number called Semester Grade Point Average (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (theory/Practical) in a semester with credits C1, C2, C3, C4, and C5and the student's grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to-

$$\text{SGPA} = \frac{C1\ G1+C2G2+C3G3+C4G4+C5G5}{C1+C2+C3+C4+C5}$$

The SGPA is calculated to two decimal points. It should be noted that the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has 'F' or 'AB' grade in course 4, the SGPA shall then be computes as:

$$\text{SGPA} = \frac{C1\ G1+C2G2+C3G3+C4*ZERO+C5G5}{C1+C2+C3+C4+C5}$$

1.16 Cumulative Grade Point Average (CGPA

The CGPA is calculated with the SGPA of all the 4 semesters to two decimal points and is indicated I final grade report card/final transcript showing the grades of all 4 semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is /ae passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.

The CGPA is calculated as:

$$\text{CGPA} = \frac{C1\ S1+C2S2+C3S3+C4S4+C5S5}{C1+C2+C3+C4+C5}$$

Where, C1, C2, C3….. is the total number of credits for semester I, II, III,…… and S1,S2,S3… is the SGPA of semester I, I, III,……

1.17 Declaration of Class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.5 and

Above First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

1.18 Project work

All the students shall undertake a project under the supervision of teacher and submit a thesis. The thesis shall be submitted in duplicate (typed and bound copy)

The internal and external examiner appointed by the university shall evaluate the thesis at the time of examinations as shown in Table No.5. (Semester-IV)

1.19 Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuring convocation.

1.20 Duration of completion of the study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

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