Master of Science - Clinical Research

Syllabus - First Semester

CLINICAL DATA MANAGEMENT

Course Code: CLR4102 **Credit Units: 04**

Course Objective:
To enrich the understanding of clinical data management procedure in clinical research which sponsor, CRO and Hospital use for clinical trials. To know the latest technology of clinical data management used in clinical trials

Course Contents:

Module-I: Introduction to Clinical Data Management and SOPs
Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data management, review and authorization. CRF design , Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs. Database design and build ,Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen validation, data entry process, symbols, data entering. Electronic clinical trials, advancement in drug discovery ,CTRI ,clinical trial for biological products and medical devices

Module-II:
Electronic data and lab data loading ,electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives , Lab data loading
Roles and responsibilities of lab loader technician, helpdesk, study coordinator, loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously.

Module-III:
Quality control of clinical data , Terminology and definitions, quality control process, data errors and quality measurement, responsibilities, operational QC, data management matrix

Module-IV:
Database lock and data transfer, Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:

- Clinical Data Management: 2nd Edition by Richard K. Rondel, Sheila A. Varley, Colin F. Webb
- Practical Guide to Clinical Data Management by Susanne Prokscha - Taylor & Francis

STATISTICS FOR CLINICAL RESEARCH

Course Code: CLR4103 **Credit Units: 04**

Course Objective:
To enrich the understanding of biostatistician procedure in clinical research which sponsor, CRO and Hospital use in clinical trials. To know the importance of biostatistics in clinical trials.

Course Contents:

Module-I:
Introduction and basic concepts ,Overview of the drug development process, bias, randomization, blinding, choice of control group. Organization and display of data, Types of data, graphical diagrammatic representation of data. Role of biostaticians in clinical research, ANOVA –Survival analysis, measurement scales and variables, sampling, degree and meaning of correlation, and its types , karl Pearson and spearman correlation coefficient ,difference b/w correlation and regression.

Module-II:
Measures of Central tendency ,Mean, median, mode, measure of dispersion ,Standard Deviation, Standard Error, Variance, range, Coefficient of Variation. Skegness & Kurtosis.

Module-III: Correlation and Regression
Correlation:, types of data required, assumptions, correlation coefficient, significance of correlation, meaningfulness of correlation coefficient. **Regression:-**, Simple linear regression.

Module-IV:
Probability and probability distributions, Definitions, probability distribution curves. Continuous probability distribution-Normal distribution, properties and applications. Discrete probability distribution-Binomial & Poisson distribution, properties and applications. Test of significance-F –test, t-test & chi-square test. Statistical input during protocol design, Demonstration of sample size calculation: comparing two means, Sample size computation

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:
Text:

- Biostatistics: A foundation for analysis in the Health Sciences, W.W Daniel. Publisher: John Wiley and Sons.
- Biostatistics, P.N Arora and P.K Malhan. Publisher: Himalaya Publishing House.

References:

- Introduction to Biostatistics, Ronald N. Forthfer and Eun Sun Lee .Publisher: Elsevier.
- Biostatistics: A foundation for analysis in the Health Sciences, W.W Daniel. Publisher: John Wiley and Sons.
- Statistical Methodology, S.P Gupta. Publisher: S.Chand & Co.
- Biostatistics: A manual of Statistical Methodology for use in Health, Nutrition and Anthropology, K. Visweswara Rao. Publisher: Jaypee Brothers.

- Fundamentals of Mathematical Statistics, S.C Gupta and V.K Kapoor. Publisher: S. Chand & Co.
- Statistical Analysis, Kaushal, T.L. Publisher: Kalyani Publishers.
- Statistical Methods, Potri, D. Kalyani Publishers.
- Mathematical Statistics by H.C. Saxena and V.K. Kapoor. Publisher: S. Chand & Co

PRACTICAL **Credit: 01**

1. Collection of data & statistical calculations
2. Preparation of charts/graphs
3. Problems based on measure of central tendency.
4. Problems based on measure of dispersion.
5. Problems based on test of significance-t-test, F-test, chi-square test.
6. Problems based on correlation & regression.
7. Problems based on Probability

BASICS OF PHARMACY, DRUG DISCOVERY AND DEVELOPMENT

Course Code: CLR4104 **Credit Units: 05**

Course Objective:
To enrich the understanding of pharmacology, drug discovery procedure in clinical research which sponsor, CRO and Hospital use for patient protection. To know the importance of drug discovery in clinical trials

Course Contents:

Module-I:
History of Pharmacy, Indian Pharmaceutical industry, Drugs-sources, nomenclature, classification, Pharmacopoeias, Formulary, Codex. Branches of Pharmacy: Pharmacognosy, Pharmaceutical chemistry, Quality Assurance, Pharmaceutics, Pharmacology, Pharmacy Management and Pharmacy Practice. Pharmaceutical Manufacturing-Quality Assurance and Quality Control.

Module-II:
Drug Regulatory Environment-Pharmaceutical Legislation in India, Drug regulatory authorities, International Conference on Harmonization, Good Practices and Quality Management, Drug Master File.

Module-III:
Drug Discovery & Development. History of drug development, Drug Discovery Pipeline, Drug Discovery Process. Approaches to Drug Discovery: Synthetic/medicinal chemistry, combinatorial synthesis, Natural Product, In Silicon approach or CADD, QSAR, Discovery Genomics.

Module-IV:
Personalized medicines, High throughput screening. Manufacturing and packaging Manufacturing-Multitasking machines Packaging-cGMP, USP requirements on containers and closures, Quality Control, Inhalation drug products, drug products for injection, drug products for ophthalmic, liquid based oral and topical drug products, post approval packaging changes.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:
- Drug Discovery and Development , 2nd Edition by Raymond G Hill
- Drugs: From Discovery to Approval by Rick Ng

Syllabus - Second Semester

PRECLINICAL STUDIES AND SAFETY

Course Code: CLR4201 **Credit Units: 05**

Course Objective:
To enrich the understanding of pre-clinical drug discovery procedure in clinical research
To know the importance of Preclinical studies and various procedure used in clinical trials

Course Contents:

Module-I:
Experimental animals used, Equipments used in ATC, Sterilization techniques, media for animal cell culture. Cell culture and cell lines, concepts in mammalian and non-mammalian culture, applications of cell culture, Assessment of preclinical data, assessment of cost benefit and risk ratio.

Module-II:
History of toxicity, relationship between dose and toxicity, types of toxicity, factors influencing toxicity, toxins, toxicity studies, special toxicity studies, in vitro models, in situ methods, in vivo models

Module-III:
Good Laboratory Practices, ICMR-GLP guidelines, FDA-GLP guidelines, Organization and personnel, facilities, equipment, testing facilities operation, test and control studies, protocol for and conduct of a non-clinical laboratory study, records and reports, disqualification of testing facilities, OECD-GLP guidelines, quality assurance program, facilities, test systems, test and reference items, Standard Operating Procedures, Performance of the study, reporting of study results, storage and retention of records and materials.

Module-IV:
Drug action, mechanism of drug action, dose-response relationship, therapeutic index, undesirable effects, disease modeling–hypertension, asthma, acidity, arthritis, cancer, addiction, autoimmune diseases, pain, epilepsy, inflammation.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:
Text:

- Basic Principles of Clinical Research and Methodology by S.K.Gupta
- Drug Discovery and Development by Raymond G Hill

IPR & DATA EXCLUSIVITY, BIOETHICS IN CLINICAL RESEARCH

Course Code: CLR4202 **Credit Units: 05**

Course Objective:
To enrich the understanding of IPR and bioethics procedure in clinical research which sponsor, CRO and Hospital use for patient protection .To know the importance of ethics and IPR law used in clinical trials .

Course Contents:
Module-I:
Intellectual property rights, Laws of IPR, patents, The World Trade Organization and the TRIPS agreement, copy rights, the rationale for IP protection, the evidence about the impact of IP, Technology Transfer, Contracts and Agreements ,CIOMS , Insurance for research injuries , contractual agreement.

Module-II:
The Data Protection Act & data mining, data and disclosure, data exclusivity, data exclusivity as a governmental function, commercial and economical rationale for test data, confidentiality, current state of data protection.

Module-III:
Introduction to bioethics, ethical issues in preclinical (animal) studies, & clinical studies-Ethical principles, Institutional Review Board, Special issues in research. Ethical Guidelines-ICMR, Institutional Ethics Committees, Institutional Review Board, Ethics-SOPs Ethical issues based on methodology of clinical Research. The ethics of clinical research in developing countries.

Module-IV:
Basic philosophies of animal ethics: (3 'R's), Animal Ethics Committee, executive, meetings, confidentiality and indemnity, period of approval, joint animal ethics committee, process to establish an AEC, guidelines for ethical conduct in the care and use of animals. Social responsibility for clinical researcher.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:
- Basic Principles of Clinical Research and Methodology by S.K.Gupta

REGULATORY AFFAIRS

Course Code: CLR4204 **Credit Units: 05**

Course Objective:
To enrich the understanding of Regulatory Affairs procedure in clinical research for global business purposes. To know the procedure of regulatory submission from CRO, Sponsor.

Course Contents:

Module-I
Introduction regulatory affairs:
Overview of judicial system in India, Medical Evidence, Legitimacy and Paternity, Privileged Communication and Professional Secrets, The Rights and Obligations of a Medical Professional to Patient, Medical Malpractice, Code of Medical Ethics.

Module-II:
The Drugs and Cosmetics Act & Schedule Y:
Introduction to Drugs and Cosmetics Act, Aims and Objectives, Definitions, Administrative bodies, Schedules to Drug Rules, Import of drugs, Manufacture of drugs, Sale of drugs, penalties for offence regarding sale of drugs, labelling and packaging of drugs . Schedule Y, Clinical trials, Studies in special populations, Post Marketing Surveillance, special studies. Bioavailability and Bioequivalence studies, Amendment of Schedule Y.

Module-III:
Food and Drug Administration (FDA):
Introduction to Food and Drug Administration, Laws Enforced by the FDA, Food and Drugs Act, Food Standards during 1930s, 40s and 50s, Center for Drug Evaluation & Research (CDER) Establishment-first step, Drug Inspection laboratory, functions and activities of CDER, post drug approval activities. Center for Food Safety & Applied Nutrition (CFSAN)CFSAN-Mission, scope of responsibility, Organization of CFSAN, Applicability of Food Safety Law, precaution in regulating animal foods, authority to reconsider data, pesticides, plant and animal health
regulations, FDA nutrition policy: labeling and fortification.

Module-IV:
Regulatory authorities & ICH:
Regulatory authorities in India Indian FDA, DCGI, Schedule Y, ICMR, GEAC, AERB, DGFT, DTAB, DBT Guidelines and other important provisions, Indian regulatory approval process, regulatory timelines, approval timeline, approval letter.ICH and Process of Harmonization: History and structure of ICH, Process of Harmonization ICH Guidelines, Categories of ICH guidelines, Quality, Safety, and Efficacy Guidelines.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & References:
1. A guide book for regulatory submission: Sandy Weinberg.
2. A guide to clinical drug research: A.Cohen & J. Posner.
3. FDA Regulatory affairs: Dougles J. Posano & David Mantus.
4. Introduction to regulatory affairs: Vedjignesh.
5. Regulatory affairs: Fegodets.

AUDIT AND INSPECTION

Course Code: CLR4206 **Credit Units: 05**

Course Objective:
To enrich the understanding of Audit and inspection procedure in clinical research for global business purposes. To know the importance of Audit and inspection for CRO, Sponsor and Hospital.

Course Contents:

Module-I: Introduction to Audits and quality assurance :
Quality Assurance, Definition, Quality system, The Quality Plan, Quality Assurance (QA), Quality Control (QC), Differentiating quality control and quality assurance, Structuring the quality assurance function, Critical Issues For Organizing The Quality Assurance Function, Overview Of QA Activities Audits: Definition of audit, Quality Assurance Audits In Clinical Research, Motives For Process Audit, Objectives Of Process Audit, Auditors, Conducting A Clinical Research Department Process Audit, Audit findings, Research Fraud and misconduct, site audits, FDA inspections, PL 483 warning letters, Auditing clinical data management function.

Module-II: Site audits, fraud and misconduct:
Definition of audits as per ICH GCP, Goals and objectives of study site audits, Types of clinical trial site audits, Criteria for onsite audits, The audit process, Audit preparation activities, Common audit findings.

Module-III: FDA Inspections, PL 483, and warning letters :
Definitions, Differentiating inspection from audits, Types of inspections, Purpose of regulatory inspections, The process of inspection, forms, warning letters, Selection of the study site for inspection, Forms, warning letters.

Module-IV: Auditing CDM function:
Types of audits in CDM, Audit process, Activity-specific audits, Protocol audit, CRF audit, Audit of the Study Database Build, DMP review, Study-specific audit, Common findings during a data management audit.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:
- Clinical trials audit-David machin
- Introduction to Audit & inspection-DJ Cockbuern
- Clinical trials audit preparation:a guide for good clinical practice inspection: Vera mihajlovic & madzarevic**.**

Syllabus - Third Semester

PROJECT MANAGEMENT AND BUSINESS DEVELOPMENT

Course Code: CLR4301 **Credit Units: 05**

Course Objective: To enrich the student role and responsibility of Project manager in clinical trials To know the importance of Project manager in clinical research

Course Contents:

Module-I: Introduction to Project Management :
The triple constraints in Project Management, Project management activities, Project objectives, Project management Documents, Project control variables, Project Management & Clinical Trials, Role of Project Management in Clinical Trials, Major Roles of a Project Manager in a CRO, Ensuring Project Success.

Module-II: Project Management Process & Project Development Plan in clinical research:
Initiating, Planning, Executing, Monitoring & Controlling, Closing .Preparation of Clinical Project Development Plan, Contents of Clinical Project Development, Plan, Review and Approval of CPDP.

Module-III: Business Development in the Clinical Research Industry:
Introduction & Stages of Business Development-Start-up Phase, Growth Phase, Maturity Phase, Decline Phase. Outsourcing in Clinical Research, Reasons for outsourcing to contract research organizations, The India Advantage, Scope and Future of CRO, List of Clinical Research Organizations in India, List of IT companies offering services in Clinical Research. Role of business development manager.

Module-IV: Clinical Research outsourcing & Services Offered by CROs:
Benefits of outsourcing, Out/In-Sourcing of Clinical Services, Process of outsourcing Phase I to Phase IV studies, Acute, Sub-acute, Chronic animal studies, Bioequivalence and Bioavailability, Clinical Trial Management, Clinical Trial Monitoring, Pharmacovigilance - Drug Safety, Data Management, Regulatory Affairs, Protocol Development, Site Management, Clinical Trial Supplies, Centralized Lab Management, Centralized ECG reading services, Centralized Imaging Services.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:
1. Project Management - The Managerial Approach: Clifford Gray and Erik W. Larson
2. Principles of project management: Richard A. Billows.
3. Principles of project management & risk management: R.Max Wideman.
4. Business development: the expanding role of the project management: Lew Ireland

SPECIAL REGULATORY PROCESS

Course Code: CLR4302 **Credit Units: 04**

Course objective: To enrich the student role and responsibility of Regulatory bodies in clinical trials To know the importance of regulatory affairs in clinical research

Course Contents:

Module-I:
IND Requirements for New Drugs, Biologics, Botanical Drug Products, Dietary Supplements (Nutraceuticals) :
IND application, FDA's role in Drug Development, Types of INDs, Categories of INDs, Content of INDs, Resources for IND Applications, Guidance Documents for INDs, Manual of Policies and Procedures (MaPPs), Laws, Regulations, Policies and Procedures, IND Forms and Instructions, Emergency use of an Investigational Drug or Biologic, FDA's Drug Review Process: Ensuring Drugs are Safe and Effective, Stages of Drug Development and Review, The Quality of Clinical Data, Drug Safety Oversight Board (DSOB), Botanical Drug Products, Global Regulatory Standards For Dietary Supplements/Nutraceuticals.

Module-II:
Compliance of Chemistry, Manufacturing, Control (CMC) Information:(a)CMC Information for IND applications for Exploratory Phase I Studies,(b)CMC Information for IND Applications for Phase II & Phase III Studies

Module-III:
Regulatory Process for cosmetics, Medical Devices and Veterinary Products
Cosmetics Regulation:
Indian Scenario-Prohibition of Import of Cosmetics, Standards of Quality, Import of Cosmetics, Manufacture of Cosmetic for Sale or for Distribution, Labeling, Packaging and Standards of Cosmetics. a) Medical Devices / Diagnostic Kits- US FDA Scenario, Indian Scenario (b) Veterinary Products- US FDA Scenario, Indian Scenario

Module-IV:
Biosimilars & Biopharmaceuticals:
EMEA, background, Guideline on Similar Biological Medicinal Products ,Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance, Guideline on Similar Biological Medicinal Products containing Biotechnology- Derived Proteins as active Substance: Non-Clinical and Clinical Issues. Indian regulations and guidance of Biopharmaceuticals – Regulatory bodies, Guidelines for generating preclinical and clinical data for r-DNA based vaccines, diagnostics and other biological.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:
1. FDA Regulatory affairs: Dougles J. Posano & David Mantus.
2. A guide to clinical drug research: A.Cohen & J. Posner.
3. Introduction to regulatory affairs: Vedjignesh.
4. A guide book for regulatory submission: Sandy Weinberg

REPORTING AND MEDICAL WRITING

Course Code: CLR4303 **Credit Units: 05**

Course Objective :
To enrich the student role and responsibility of medical writer in clinical trials. To know the importance of medical writer in clinical research.

Course Contents:

Module-I:
Fundamentals of Medical Writing & Data interpretation and presentation:
The Scope of Medical Writing, Qualities of effective medical writer, Types of Data, Tools of data presentation Graphical methods for qualitative data: Frequency Tables, Pie Charts, Bar charts, Comparing Distributions, Graphical methods for quantitative data: Stem and leaf plots, Histograms, Line Graphs Error, Bookmark not defined. Dot plots Error, Bookmark not defined. Box Plot, Scatter Plot.

Module-II:
The Clinical Study Report & Reporting clinical laboratory tests:
Structure of CSR and possible modifications, study patients, efficacy evaluation, safety evaluation, discussion and overall conclusions, tables, figures and graphs referred to but not included in the text, reference list, appendices. Reference ranges (normal ranges), Interpretation of normal values, Units of measurement, Factors Affecting interpretation of test.

Module-III:
Preparation of Investigator's Brochure, clinical summaries and global submission dossiers:
Contents of the Investigator's Brochure, Table of Contents, Summary, Introduction, Physical, Chemical, and Pharmaceutical Properties and Formulation, Non-clinical Studies, Effects in Humans, Summary of Data and Guidance for the Investigator Components of the CTD, Global Submission Dossiers, Electronic Common Technical Document

Module-IV:
Bibliography preparation ,Computer skills & Language for medical writers :
Types of referencing – Primary and secondary, standard referencing. Different styles of referencing – Focus on Vancouver style.MS word ,MS Excel & MS PowerPoint skills –complete knowledge & skills for typing, tabulation, slide show & animation preparation. Basic language orientation-Sentence Structure and Patterns, Choice of active or passive voice, proper use of tenses. Punctuation for Clarity and Style–types of punctuation, capitalization, use of hyphens, quotation marks, apostrophes, commas, and differences between British and American English. Techniques to improve simplicity and clarity of style-linking of passages and construction of paragraphs, building of strong sentences.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:
1. Clinician's Guide to Medical Writing :Robert B. Taylor. 1st ed. 2004. Springer Publications.
2. Guidebook to Better Medical Writing :Robert L. Iles (Author), Debra Volkland. Iles
3. Medical writing & clinical reporting: Beltas.
4. Medical writing: Cam Johns tan.
5. Medical writing & reporting:Dr.Nancy Snyder man.

PHARMACOGENOMICS

Course Code: CLR4304 **Credit Units: 04**

Course Objective:
To enrich the student important role of pharmacogenomics in drug discovery in clinical trials
To know the importance of pharmacogenomics in clinical research

Course Contents:
Module-I: Introduction to pharmacogenomics:
History, Chronology of Events, Pharmacogenetics and Pharmacogenomics: The Difference, Benefits of Pharmacogenetics, Pharmacogenetics in Practice, Promise of Pharmacogenomics, Limitations, Pharmacogenomics drugs in the market, Future of Pharmacogenomics

Module-II: Determinants of drug response & Bioinformatics tools for pharmacogenomics:
Pharmacokinetics and pharmacodynamics of drug, drug properties that influence its pharmacokinetics and pharmacodynamics .Bioinformatics, Divisions of Bioinformatics, Fields Related to Bioinformatics, Application of Bioinformatics in various disciplines/fields, Major categories of Bioinformatics Tools with examples

Module-III: Pharmacogenetics of enzymes and transporters:
Xenobiotic -Phase I and II reactions Drug transporters-Structure and model of drug transporters, transport mechanisms, polarized expression of drug transporters, drug transporters in barrier epithelium, classification of drug transporters, ABC and SLC transporters, genetic variation and drug response, genetic variation in membrane transporters

Module-IV: Clinical pharmacogenomics and clinical trials:
Pharmacogenomics in clinical practice, the role of drug metabolizing enzymes in cardiovascular pharmacology, Pharmacogenetics and clinical trials-Issues in clinical trials ethical implications of pharmacogenomics research, guidance on pharmacogenomics data.

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:
1. Basic and Clinical Pharmacology :Bertrand Katzung
2. Essentials of Medical Pharmacology :K. D Tripathi
3. Pharmacology: Rang, Dale and Ritter
4. Pharmacology and Pharmacotherapeutics:Satoskar,18th ed, 2003

PHARMACOVIGILANCE AND SAFETY MONITORING

Course Code: CLR4305 **Credit Units: 04**

Course Objective:
To enrich the student role and responsibility of Pharmacovigilance and various safety monitoring's in clinical trials .To know the importance of Pharmacovigilance in clinical research.

Course Contents:

Module-I: Introduction to Pharmacovigilance:
Introduction, Definition, requirement of Pharmacovigilance needed, Objectives of Pharmacovigilance, and Agencies concerned with Pharmacovigilance, Reporting ADRs, changes to recommendations for use, Methods involved in Pharmacovigilance, Pharmacovigilance plans, Scope of Pharmacovigilance, Indian scenario, Pharmacovigilance and pharmacogenomics.

Module-II: Safety monitoring process & good Pharmacovigilance Practices (GPP) :
The Monitoring Process, the Role of Institutional Review Boards and Data Safety Monitoring Boards, Quality Assurance Monitoring, Ending Trials Early: Protecting the Interests of Participants and the Public. GPP, Overview of Risk Management Goals and Guidance, Adverse events, serious adverse events, Reporting of AE & SAE.

Module-III: Good reporting practices and safety signals:
Risk management process, Signals, Case report, Case series, Causality, Data mining, Reporting rates Vs. incidence rates, Pharmacovigilance plans, Pharmacoepidemiological safety studies

Module-IV: Pharmacoepidemiology, Registers, Surveys :
Pharmacoepidemiology, Guidelines for Good Pharmacoepidemiology Practices (GPP), Pharmacovigilance Methods, Use of health care databases in Pharmacoepidemiology, Registries, Surveys, Pharmacoeconomics and pharmacoepidemiology, Pharmacoepidemiology and pharmacokinetics, International drug monitoring, Using eHealth information for comprehensive Pharmacovigilance surveillance, Pharmacoepidemiology in India, Pharmacovigilance and India

Examination Scheme:

Components	CT	Attendance	Assignment/ Project/Seminar/Quiz	EE
Weightage (%)	15	5	10	70

Text & Reference:

- Textbook of therapeutics Drug and Disease Management: Eric T Herfindel, Dick R. Gourley, 6th ed.
- Assuring Data Quality And Validity In Clinical Trials For Regulatory Decision Making : Janet Woodcock, Frederick Ognibene, John Overbeke.2003;Welly Publication.

SUMMER INTERNSHIP

Course Code: CLR4335 **Credit Units: 06**

GUIDELINES FOR SUMMER TRAINING

The main objective of summer training is to familiarize students to laboratory environment and make them learn to handle equipments and softwares, design experiments and analyze the results. The student will be supervised by one or more faculty members and he or she will be required to submit a synopsis. While writing a synopsis emphasis should be given to make it publishable. But whether or not the results of a research project are publishable, the project should be communicated in the form of a research report written by the student. Initial drafts should be critiqued by the faculty guide and corrected by the student at each stage.

The File is the principal means by which the work carried out will be assessed and therefore great care should be taken in its preparation.

In general, the File should be comprehensive and include

- A short account of the activities that were undertaken as part of the project;
- A statement about the extent to which the project has achieved its stated goals.
- A statement about the outcomes of the evaluation and dissemination processes engaged in as part of the project;
- Any activities planned but not yet completed as part of the project, or as a future initiative directly resulting from the project;
- Any problems that have arisen that may be useful to document for future reference.

Report Layout

The report should contain the following components:

- TITLE PAGE
- CERTIFICATE
- ACKNOWLEDGEMENT
- ABBREVIATIONS
- CONTENTS WITH PAGE NUMBERS
- CHAPTER –
    a. INTRODUCTION
    b. REVIEW OF LITERATURE
    c. MATERIALS & METHODS
    d. RESULTS & DISCUSSION
    e. SUMMARY AND CONCLUSION
    f. REFERENCES
    g. APPENDIX (OPTIONAL)
- 1 inch Margin on left side & 1”each on other sides.
- Single side of the paper to be used.
- Times New Roman.

Font Size

- 12 (Bold for headings)
- 12 (Normal for Matter)
- 14 (for Chapter Names)
- 1.5 line spacing
- Numbering on the right hand Top of the page
- Numbers on pages before chapters to be done in Roman at the bottom of the page

References
This should include papers and books referred to in the body of the report. These should be ordered alphabetically on the author's surname. The titles of journals preferably should not be abbreviated; if they are, abbreviations must comply with an internationally recognised system.

Examples

For research article
Voravuthikunchai SP, Lortheeranuwat A, Ninrprom T, Popaya W, Pongpaichit S, Supawita T. (2002) Antibacterial activity of Thai medicinal plants against enterohaemorrhagic *Escherichia coli* O157: H7. *Clin Microbiol Infect*, **8** (suppl 1): 116–117.

For Book
Kowalski,M.(1976) Transduction of effectiveness in *Rhizobium meliloti*. SYMBIOTIC NITROGEN FIXATION PLANTS (editor P.S. Nutman IBP), 7: 63-67

- Scientific names in Italics
- Cover Page containing - Title, Students Name, Supervisors Name, University, Name (along with logo), Course name & year of Submission in the prescribed format
- 2 copies to be submitted

ASSESSMENT OF THE PROJECT FILE
Essentially, marking will be based on the following criteria: the quality of the report, the technical merit of the project and the project execution.. Evaluation will compose of two components - Project report assessment and Viva - voce. Project report assessment will be done by the two internal faculty members in respective fields. A committee of three faculty members will conduct Viva-voce.
Technical merit attempts to assess the quality and depth of the intellectual efforts put into the project will be assessed as per evaluation format.

Examination Scheme:

Project Report	50
Viva Voce	50
Total	**100**

Syllabus - Fourth Semester

DISSERTATION

Course Code: CLR4437 **Credit Units: 20**

GUIDELINES FOR PROJECT FILE

Research experience is as close to a professional problem-solving activity as anything in the curriculum. It provides exposure to research methodology and an opportunity to work closely with a faculty guide. It usually requires the use of advanced concepts, a variety of experimental techniques, and state-of-the-art instrumentation.

Research is genuine exploration of the unknown that leads to new knowledge which often warrants publication. But whether or not the results of a research project are publishable, the project should be communicated in the form of a research report written by the student.

Sufficient time should be allowed for satisfactory completion of reports, taking into account that initial drafts should be critiqued by the faculty guide and corrected by the student at each stage.

The File is the principal means by which the work carried out will be assessed and therefore great care should be taken in its preparation.

In general, the File should be comprehensive and include

- A short account of the activities that were undertaken as part of the project;
- A statement about the extent to which the project has achieved its stated goals.
- A statement about the outcomes of the evaluation and dissemination processes engaged in as part of the project;
- Any activities planned but not yet completed as part of the project, or as a future initiative directly resulting from the project;
- Any problems that have arisen that may be useful to document for future reference.

Report Layout

The report should contain the following components:

- **Title or Cover Page**

The title page should contain the following information: Project Title; Student's Name; Course; Year; Supervisor's Name.

- **Acknowledgements** (optional)

Acknowledgment to any advisory or financial assistance received in the course of work may be given.

- **Abstract**

A good "Abstract" should be straight to the point; not too descriptive but fully informative. First paragraph should state what was accomplished with regard to the objectives. The abstract does not have to be an entire summary of the project, but rather a concise summary of the scope and results of the project

- **Table of Contents**

Titles and subtitles are to correspond exactly with those in the text.

- **Introduction**

Here a brief introduction to the problem that is central to the project and an outline of the structure of the rest of the report should be provided. The introduction should aim to catch the imagination of the reader, so excessive details should be avoided.

- **Materials and Methods**

This section should aim at experimental designs, materials used. Methodology should be mentioned in details including modifications if any.

- **Results and Discussion**

Present results, discuss and compare these with those from other workers, etc. In writing these section, emphasis should be given on what has been performed and achieved in the course of the work, rather than discuss in detail what is readily available in text books. Avoid abrupt changes in contents from section to section and maintain a lucid flow throughout the thesis. An opening and closing paragraph in every chapter could be included to aid in smooth flow.

Note that in writing the various secions, all figures and tables should as far as possible be next to the associated text, in the same orientation as the main text, numbered, and given appropriate titles or captions. All major equations should also be numbered and unless it is really necessary never write in "point" form.

- **Conclusion**

A conclusion should be the final section in which the outcome of the work is mentioned briefly.

- **Future prospects**

- **Appendices**

The Appendix contains material which is of interest to the reader but not an integral part of the thesis and any problem that have arisen that may be useful to document for future reference.

- **References/ Bibliography**

This should include papers and books referred to in the body of the report. These should be ordered alphabetically on the author's surname. The titles of journals preferably should not be abbreviated; if they are, abbreviations must comply with an internationally recognised system.

Examples

For research article

Voravuthikunchai SP, Lortheeranuwat A, Ninrprom T, Popaya W, Pongpaichit S, Supawita T. (2002) Antibacterial activity of Thai medicinal plants against enterohaemorrhagic *Escherichia coli* O157: H7. *Clin Microbiol Infect*, 8 (suppl 1): 116–117.

For book

Kowalski, M. (1976) Transduction of effectiveness in *Rhizobium meliloti*. SYMBIOTIC NITROGEN FIXATION PLANTS (editor P.S. Nutman IBP), 7: 63-67

ASSESSMENT OF THE PROJECT FILE

Essentially, marking will be based on the following criteria: the quality of the report, the technical merit of the project and the project execution.

Technical merit attempts to assess the quality and depth of the intellectual efforts put into the project.

Project execution is concerned with assessing how much work has been put in.

The File should fulfill the following ***assessment objectives:***

Range of Research Methods used to obtain information

Execution of Research

Data Analysis
Analyse Quantitative/ Qualitative information
Control Quality
Draw Conclusions

Examination Scheme:

Project Report	50
Viva Voce	50
Total	**100**