SYLLABUS

M.S. (Pharm.)
Pharmacology & Toxicology

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
GUWAHATI
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M.S. (Pharm.)
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Course No.	Course Name	Credits
Semester-I		
PC 510	Pathophysiology	1
PC 520	General Pharmacology	2
PC 530	Experimental & Molecular Pharmacology	2
PE 520	Biopharmaceutics and Pharmacokinetics	2
GE 510	Biostatistics	2
GE 520	Fundamentals of Intellectual Property (IP) & Technology Management	1
GE 511	Seminar	1
LG510	General Laboratory Experience-15 hours/week	3
	Elective	2
	TOTAL CREDITS	***16***
Semester-II		
PC 620	CNS and Respiratory Pharmacology	2
PC 630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2
PC 640	Autacoid and Endocrine Pharmacology	1
PC 650	Clinical Pharmacology and Regulatory Toxicology	2
PC 660	Pharmacological Screening and Assays	1
GE 611	Seminar	1
LS 610	General Laboratory Experience15hours/week	3
	Elective	2
	TOTAL CREDITS	**14**
Semester-III		
Project (22 weeks)		
TH-598	Synopsis	5
TH-599	Presentation	3
	TOTAL CREDITS	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	TOTAL CREDITS	**12**
GRAND TOTAL CREDITS (I to IV Semesters)		**50**

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Semester-I

PC-510 :- Pathophysiology (1 Credit)

Chapter 1: Fundamentals and recent advances of understanding the disease pathogenesis

Chapter 2: Pathophysiology and molecular basis of cardiovascular disorders (Angina, hypertension, arrhythmia, congestive heart failure, hyperlipoproteinemias); gastrointestinal disorders (peptic ulcer, pancreatitis, inflammatory bowel disease), hepatic diseases, bronchial asthma, neurological diseases (depression, schizophrenia, epilepsy), neurodegenerative disorders (Alzheimer's disease, Parkinson's disease, Amyotrophic Lateral Sclerosis, Huntington Disease, Multiple Sclerosis), endocrine disorders (disorders of thyroid glands, adrenal glands, diabetes etc), rheumatoid arthritis, gout and anaemia.

Recommended Books/Literature:

PC-520:- General Pharmacology (2 Credits)

Chapter 1: Introduction to pharmacology: ADME and factors influencing disease conditions.

Chapter 2: Concept of receptors as a drug target, Receptor classifications, structure, drug receptor interaction, G-protein, receptor characterization, receptor theories, agonist, antagonist

Chapter 3: GPCR- Classification, Receptor regulation: GPCR desensitization, down regulation, up regulation, Regulators of Gprotein signaling

Chapter 4: Ion channels and Ion channels linked receptors and their regulation

Chapter 5: Nuclear receptors and
Transmembrane signaling mechanisms, Second messenger system

Chapter 6: Transcription factors with special emphasis to Nrf2 and NF-kB, Mechanism of transcription factors, pharmacological target and role in different diseases conditions

Chapter 7: Membrane Transporters and Drug Response

Chapter 8: Dose response relationship and different type of antagonism

Chapter 9: Efficacy and Toxicity evaluation using different experimental models, dose-response analysis, margin of safety in pre-clinical development.

Chapter 10: Drug discovery, the Pharmaceutical Industry and Regulation

Recommended Books

PC-530:- Experimental and Molecular Pharmacology (2 Credits)

Chapter 1: In vivo Experiments

a) **Laboratory animals:** Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratoryanimals, Common lab animals: Description and applications of different species and strains of animals. 3 R's concept, alternatives to animal experimentations, Organs-on-chips. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drugadministration in laboratory animals, Techniques of blood collection including cannulation techniques and euthanasia

b) **Dose calculations and rational for animal species selection:** Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

Chapter 2: ***In vitro experiments***

a) **Cell free and Cell based assays (**Introduction to Primary and secondary culture). Applications of cell culture for drug screening. Cell viability studies.

b) **Experimental Molecular Techniques:** Western blotting, Northern and Southern Hybridisation, ELISA, RT PCR, Flowcytometer, Surface Plasmon Resonance, Tissue micro array etc., High Content screening.

c) Imaging techniques in pharmacological research

Recommended Books/Literature

PE-520:- Biopharmaceutics and Pharmacokinetics (2 Credits)

1. **Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rate compartment models, biological half-life, elimination rate constant. Biopharmaceutics and pharmacokinetics in drug research.
2. **GIT Absorption of drugs**: Mechanism, physico-chemical, biological and pharmaceutical factors affecting drug absorption through GIT. Techniques for the GIT absorption assessment **.**
3. **Drug disposition**: Total body clearance, renal clearance, mechanism of clearance, clearance ratio, factors affecting renal clearance, hepatic clearance, volume of distribution and its significance**.**

4. **Protein and tissue binding:** Factors affecting protein binding, kinetics of protein binding, determination of rate constant and different plots (direct, scatchard and reciprocal), Implication of protein binding on pharmacokinetic parameters.
5. **Bioavailability and Bioequivalence**: Definitions, federal requirements, methods of determination of bioavailability using blood and urinary excretion data. Protocol design for bioavailability assessment. Methods for bioequivalence determination.

   Protocol design for bioavailability and bioequivalence assessment. Methods for bioequivalence determination. Regulatory perspective of design acceptance and BE determination - BCS based approach to avoid human PK study for BE determination.
6. **Pharmacokinetic characterization of drugs:** Pharmacokinetics of drugs following one/two compartment open models with first order elimination kinetics as applied to rapid intravenous injection, Intravenous transfusion and oral administration. Determination of absorption rate constant using Wagner-Nelson, Loo Riegelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs. Pharmacokinetics of multiple dosing. Pharmacokinetics of modified/sustained release dosage forms.
7. **Dosage regimen:** Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in elderly, children, and obese patients.
8. **Non-Linear Pharmacokinetics:** Various causes of non-linearity, Michaelis-Menten kinetics, In-vivo estimation of Km and Vm. Lineweaver Burk equation.
9. **Physiologic pharmacokinetics models:** Mean Residence Time (MRT); Statistical moment theory; Mean absorption time (MAT); Mean dissolution time (MDT); Lagrange and spline method Application and limitations of physiologic pharmacokinetic models.
10. **Miscellaneous Topics:** Chronopharmacokinetics, Drug toxicity and forensic pharmacokinetics, kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/ clinical response, metabolic kinetics

Recommended Books

1. Applied biopharmaceutics pharmacokinetics. LEON SHARGEL AND ANDREW B.C. YU, 2016, 7th Edition.
2. Foundation of Pharmacokinetics. Rescigno, A. 2003.
3. Handbook of Bioequivalence Testing. Sarfaraz K. Niazi. 2007, 1st Edition.
4. Biopharmaceutics and Relevant Pharmacokinetics. Wagner, J. G. 1970.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics. Niazi, S.K. 1980.
6. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches. Macheras, P. and A. Iliadis, 2016, 2nd Edition.
7. Comparative Pharmacokinetics: Principles, Techniques and Applications. Riviere, J.E., 2011, 2nd Edition.
8. Introduction to Biopharmaceutics. Gibaldi, M. 1971.
9. Biopharmaceutics and Pharmacokinetics: An Introduction. Notari, R. E.2008.
10. BA/BE guidance of US FDA and EMEA, BCS waiver guidance by USFDA

GE-510 :- Biostatistics (2 Credits)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation**.**
2. **Probability:** Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling:** Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. **Estimation and Hypothesis testing:** Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student-t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance**: Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. **Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. **Statistical techniques in pharmaceutics:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

Recommended Books:

1. Fundamentals of Biostatistics by Bernard Rosner.
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon.
3. Statistical Misconceptions by Huck GE-520 Fundamentals of Intellectual Property (IP) and Technology

GE-520 :- Fundamentals of Intellectual Property (IP) and Technology Management (1 Credit)

1. **Intellectual property**: Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property- patents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IPin pharmaceutical industry; Global ramifications and financial implications.
2. **Trade related aspects of intellectual property rights**: Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights),TRIMS(Trade Related Investment Measures) and GATS(General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
3. **Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS:** Filing of a patent application; Precautions before patenting- disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs;

Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infrigment- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

4. **Technology Development/transfer/commercialisation related aspects:** Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary licensing excess to medicine issues; DOHA declaration, POSTWTO product patentregime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies antiretroviral drugs and others.
5. **Funding sources for commercialization of technology:** Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT,CCMB, IMTECH, NIPER. Documentation and related aspects.
6. **Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benifits of modern biotechnology; Voluntary adoption of pollution control strategies. 49 60 Courses of Study 2015.

Recommended Books:

1. Law Relating to Intellectual Property by B.L.Wadhera.
2. IPR Handbook for Pharma Students and Researchers by P.Bansal.
3. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012).
4. Patent Agent Examination by Sheetal Chopra and Akash Taneja.
5. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan.
6. Making Breakthrough Innovation Happen by Porus Munshi.

7. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson.
8. Legal Drafting for the Layman by Nabhi Kumar Jain.
9. How to Write and Publish a Scientific Paper by Rober A Day.
10. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V.Chandrachud.
11. Biomedical Research- From Ideation to Publication by G.Jagadeesh and others.

GE-511 :- Seminar (1 Credit)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
4. Reading research papers.
5. Skills in oral presentation.

Each student has to present a seminar before end of the semester.

LG-510 :- General Laboratory Experience (3 Credits)

1. **Analytical Techniques (75 hours):**
   - **a)** Spectral analysis workshop (45 hours).
   - **b)** Separation techniques (30 hours).
2. **Computer and application in pharmaceutical sciences (100 hours):** Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):** Day -1: Preparation for plasmid miniprep. Day-2: Plasmid miniprep and restriction digestion. Day-3: Gel electrophoresis and molecular weight calculation. Day-4: Discussion of result and viva.
5. **Specialization (50 hours):**
   a) To prepare granules by dry granulation using Roller compactor.
   b) To optimize wet granulation process and perform scale up using Rapid Mixer Granulator (RMG)
   c) Study the dissolution behaviour/ drug release pattern of various conventional, sustained release, enteric coated and nanoparticulate dosage form and establishment of dissolution kinetics. Study of various factors affecting dissolution / drug release
   d) Study of drug protein binding and effect of competitive agent on binding kinetics
   e) Plotting and interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter

M.S. (Pharm.) Pharmaceutics
Semester - II

PC-620:- CNS AND RESPIRATORY PHARMACOLOGY
(2 Credits)

Unit 1: CNS drug discovery and challenges
Unit 2:Neurotransmitters, and their receptors (5-HT, excitatory amino acids, GABA, glycine, cannabinoids, melatonin), peptides as mediators (substance P, neuropeptide Y, somatostatin, cholecystokinin, neurotensin, enkephalin, Orexin, CGRP,
nerve growth factors, etc),
neuromodulators, neuromediators and transporters
Unit 3: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of antianxiety drugs, antidepressants, antipsychotic drugs, psychomotor stimulants
Unit 4: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of anti-epileptics
Unit 5: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of antimigraine drugs,
Unit 6: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of local anesthetics, general anesthetics, centrally acting muscle relaxants
Unit 7: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of narcotic analgesics
Unit 8: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Alzheimer's disease, Parkinson's disease, Huntington's disease, Multiple sclerosis
Unit 9: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Stroke
Unit 10: Gene therapy and cell-based therapy for CNS disorders
Unit 11: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in asthma, COPD and cough.

Recommended Books/Literature:

PC-630 :- AUTONOMIC, CVS, BLOOD, RENAL AND GI PHARMACOLOGY, CREDITS
(2 Credits)

Chapter 1: Introduction to Autonomic Pharmacology:
Neurotransmission: The Autonomic and Somatic Motor Nervous Systems, pharmacology of Muscarinic Receptor Agonists and Antagonists, Anticholinesterase Agents, Pharmacology of Ganglionic stimulants and blocking agents, neuromuscular blocking agents, Pharmacology of adrenergic agonists and antagonists

Chapter 2: Introduction to CVS Pharmacology: CVS drug discovery and challenges, Antihypertensive drugs and newer targets for hypertension, Antianginal drugs and newer targets for myocardial infarction, Drugs for Heart failure and antiarrhythmic drugs, Pharmacology of Lipid lowering and anti-obesity agents, CVS disease models and evaluation of effect of NCEs

Chapter 3: Factors necessary for erythropoiesis: Homopoietic growth factors. Mechanism of blood clotting, hematopoietic agents, Oral anticoagulants: Factors increase/decrease the efficacy of oral anticoagulants, Heparin, Platelet adhesion and activation: Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents, integrins as therapeutic agents

Chapter 4: Renal Pharmacology: Diuretics, vasopressin

Chapter 5: Pharmacology of GI drugs: Drugs for peptic ulcer, emetics, antiemetics, drug regulating GI motility, GI disease models for evaluation of effects of
NCEs

Recommended Books/Literature:

PC-640:- AUTACOIDS AND ENDOCRINE PHARMACOLOGY (1 Credit)

1. Introduction to autocoids
2. Pharmacology of histamine &bradykinin: receptors, agonists and antagonists
3. Pharmacology of eicosanoids: COX inhibitors. Pain and inflammatory models for screening
4. Adenohypophyseal hormones and related substances.
5. Thyroid and antithyroid drugs.
6. Insulin and oral hypoglycaemic agents, Endocrine pancreas.
7. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
8. Agents affecting the calcification estrogen, progesterone and androgens: their antagonists, Oral contraceptives

Recommended Books/Literature:

PC-650 :- CLINICAL PHARMACOLOGY AND REGULATORY TOXICOLOGY (2 Credits)

Chapter 1: Introduction to clinical pharmacology: Investigational new drug (IND) pplication, clinical trials (Phase I to Phase IV), new drug application (NDA) requirements, Regulatory agencies

Chapter 2: Pharmacovigilance, GCP Guidelines and GLP Guidelines, Individualization of drug therapy: Personalized medicine

Chapter 3: Preclinical testing strategy; Vis- -vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing

Chapter 4: Single dose and repeat dose toxicity studies: Factors influencing such studies such as species, sex, route, dose level; Data evaluation and regulatory requirements.

Chapter 5: Reproductive toxicology assessment of male reproductive toxicity: Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity

Chapter 6: Mutagenicity:
Mechanisms of mutagenesis, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, in vivo micronucleus tests in rodent, metaphase analysis.

Chapter 7: Carcinogenicity: Principles of carcinogenicity, dosesetting for arcinogenesis bio-assay, transplacental carcinogenesis; Cocarcinogenisis/tumor promotion.

Chapter 8: Toxicokinetics, animals and dose groups: Exposure measurement; determination of metabolites complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereoisomerism vis- -vis regulatory requirements; Singleenantiomers; Racemate enantiomer switch; Regulatory requirements.

Chapter 9: Preclinical toxicological requirements for biological and biotechnological products: Safety analysis; problems specific to recombinant products secondary pharmacology

Chapter 10: Safety Pharmacology - ICH S7 and S7B guidelines: Safety pharmacological studies for pharmaceuticals, Safety pharmacological studies for biological products

Recommended Books/Literature:

PC-660 (*Previously PC-611*):- PHARMACOLOGICAL SCREENING AND ASSAYS (1 Credit)

1.

Recommended Books/Literature:

1. **Role of Pharmacology in drug discovery and approaches for target identification & Validation**
2. **Preclinical screening models:** a) for CNS activity- analgesic, antipyretic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease **b)** for CVS activity- antihypertensives, antiarrhythmatic, antidyslepidemic, and anticoagulants **c)** for other important drugs like antiulcer, antidiabetic, antiinflammatory, and anticancer

3. **Drug Metabolism Studies:** Metabolic stability studies, CYP enzyme inhibition studies and CaCo-2 cell permeability assay.

4. **Zebrafish model to screen pharmaceutical molecules**

5. Correlations between various animal models and human situations.

6. Correlation between *in-vitro* and *invivo* screenings

GE-611:- Seminar (1 Credit)

Students are required to submit a written record and present details of the project to be pursued in semester-III & IV. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it and process for the project itself.

LS-610:- GENERAL LABORATOR EXPERIENCE (3 Credits)

03 Credits …15 hrs/week

1. Demonstration of preclinical screening of following models a) Carrageenan induced paw edema model b) STZ induced diabetes c) PTZ/MES induced convulsant activity d) analgesic activity by Hot & Cold plate d) muscle relaxant activity by rota rod e) antidepressant activity by forced swim test or tail suspension test f) demonstration of blood pressure recording and ECG g) locomotor activity by actophotometer h) antianxiety in elevated plus maze.
2. Isolation of PBMC cells, *In vitro* drug screening for antiinflammatory, antidiabetic, organoprotective
3. Biochemical assays: SOD, catalase, GSH, ROS, lipid peroxidation, NO
4. Demonstration of flow cytometer, RTPCR, confocal microscope and western blotting

Demonstration of various imaging modalities like ultrasound, optical imaging and microCT.