M.Sc. in Translational Medicine

The PG program in Translational Medicine is designed to equip students with the knowledge and skills to bridge the gap between basic scientific research and the development of medical applications/products through translational research pathways. The curriculum typically includes a combination of core courses, and hands-on research experiences. The students become experts in interdisciplinary research, acquire knowledge of GLP logistics, regulatory issues, GMP exposure for product manufacturing as well as clinical exposure relevant to medical translation. Industrial exposure is also part of the program. The curriculum is designed according to the national education policy guidelines incorporating flexibility with respect to the opportunity to exit after one year with a post graduate diploma following obtaining the required credits.

Students can expect to be placed in medical device industries, pharmaceutical industries, digital health industries or they can pursue advanced studies at the PhD level or explore startups in the medical field. Top students will receive scholarships.

Curriculum
## First Semester

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**Total** 20

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**Total** 20

## Fourth Semester

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**Total** 20

**Total Credits 81
**Preamble**
Introduction to Translational Medicine is a graduate-level course designed to provide students with a comprehensive understanding of the principles, methodologies, and applications of translational medicine. Translational medicine bridges the gap between basic research findings and clinical applications, aiming to improve patient care and outcomes. This course will cover various aspects of translational medicine, including the process of translating scientific discoveries into clinical practice, the role of interdisciplinary collaboration, ethical considerations, and current trends in the field.

**Syllabus:**

**Unit 1:**
Introduction to Translational Medicine; Definition and significance, Historical perspective.

**Unit 2:**
Bench to Bedside: The Translational Continuum; Basic research, Preclinical studies, Clinical trials, Implementation in clinical practice.

**Unit 3:**
Methodologies in Translational Medicine, Biomarker discovery and validation, Omics technologies (Genomics, Proteomics, Metabolomics), Imaging techniques, Computational modeling and simulation

**Unit 4:**
Challenges in Translational Research, Regulatory hurdles, Intellectual property issues,

**Unit 5:**
Interdisciplinary Collaboration in Translational Medicine, Team science approach, Collaboration between academia, industry, and healthcare institutions.

**Unit 6:**
Ethical Considerations in Translational Medicine; Informed consent, Data privacy and confidentiality, Equity and access to healthcare innovations

**Unit 7:**
Current Trends and Future Directions; Precision medicine, Personalized therapies, Data-driven approaches, Global health implications.

**Textbooks**

**Course outcome**

**CO1:** To understand the concept and significance of translational medicine.
**CO2:** To explore the continuum from basic research to clinical applications.
**CO3:** To examine the methodologies and approaches used in translational medicine.
**CO4:** To analyze the challenges and opportunities in translating scientific discoveries into clinical practice.
**CO5:** To discuss the role of interdisciplinary collaboration in translational research.
**CO6:** To evaluate ethical, regulatory and quality standard considerations in translational medicine.
**CO7:** To review current trends and advancements in the field of translational medicine.

**Program outcome (PO)**

**PO1:** Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
**PO2:** Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
**PO3:** Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

3 = High Affinity, 2 = Medium Affinity, 1 = Low Affinity, - = No Affinity

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Program Specific Outcome (PSO)
PSO1: Addresses the complexity of interdisciplinary sciences in biological and medical contexts.
PSO2: Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.
PSO3: Covers compounds as drugs and their efficacy, involving pharmacology and drug development.
PSO4: Explores the intersection of bioinformatics and artificial intelligence in biology and medicine.
PSO5: Deals with technology in personalizing medicine, involving precision medicine approaches.
PSO6: Focuses on communicating and disseminating science and medicine to the public, involving science communication and public outreach efforts.

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24TM502 Cell and Molecular Biology 3 0 0 3

Preamble
Advanced Topics in Cell and Molecular Biology is a graduate-level course designed to provide students with an in-depth understanding of the fundamental principles and recent advances in
cellular and molecular biology. The course will cover topics ranging from cell structure and function to molecular mechanisms underlying cellular processes, with an emphasis on critical analysis of current research literature. Through lectures, discussions, and laboratory exercises, students will explore cutting-edge techniques and applications in the field.

**Syllabus:**

**Unit 1:**
Introduction to Cell Biology; Cell structure and organelles, Membrane dynamics and trafficking, Cytoskeleton and cell motility.

**Unit 2:**
Molecular Biology of Gene Expression, Transcriptional regulation, RNA processing and translation, Epigenetics and chromatin remodeling.

**Unit 3:**
Cell Signaling and Communication, Receptor-mediated signaling pathways, Intracellular signaling cascades, Cell-cell communication and intercellular signaling.

**Unit 4:**
Cell Cycle Regulation and Cell Division; Cell cycle checkpoints and regulation, Mitosis and cytokinesis, Cell cycle control and cancer.

**Unit 5:**
Stem Cells and Developmental Biology; Stem cell niches and pluripotency, Differentiation and lineage commitment, Regeneration and tissue repair.

**Unit 6:**
Cancer Biology and Oncogenes; Hallmarks of cancer, Oncogenes and tumor suppressor genes, Cancer stem cells and therapeutic implications.

**Unit 7:**
Techniques in Cell and Molecular Biology; Immunofluorescence and microscopy, Western blotting and protein analysis, PCR, qPCR, and gene expression analysis.

**Unit 8:**
Emerging Topics in Cell and Molecular Biology; Single-cell analysis techniques, CRISPR/Cas9 genome editing, Organelle dynamics and cell imaging.

**Textbooks**

**Course outcome**

**CO1:** To gain a comprehensive understanding of cell structure, function, and organization.

**CO2:** To explore molecular mechanisms governing cellular processes such as gene expression, signal transduction, and cell cycle regulation.

**CO3:** To examine recent advances in areas such as stem cell biology, developmental biology, and cancer biology.

**CO4:** To develop critical thinking and analytical skills through the evaluation of primary research literature.

**CO5:** To gain hands-on experience with laboratory techniques commonly used in cell and molecular biology research.

**Program outcome (PO)**

**PO1:** Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

**PO2:** Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

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Emphasis will be placed on practical applications through hands-on exercises and real-world examples.

**Syllabus:**

**Unit 1:**
Introduction to Biostatistics, Definition and scope of biostatistics, Descriptive vs. inferential statistics, Levels of measurement.

**Unit 2:**
Study Designs in Biomedical Research; Observational studies (cross-sectional, case-control, cohort), Experimental studies (randomized controlled trials), Study biases and confounding factors.

**Unit 3:**
Data Collection and Management; Data sources and sampling techniques, Data collection instruments, Data cleaning and quality control.

**Unit 4:**
Descriptive Statistics; Measures of central tendency and dispersion Frequency distributions and graphical presentation of data, Probability distributions.

**Unit 5:**
Inferential Statistics; Hypothesis testing, Confidence intervals, Parametric vs. non-parametric tests.

**Unit 6:**
Regression Analysis; Simple linear regression, Multiple linear regression, Logistic regression.

**Unit 7:**
Survival Analysis; Kaplan-Meier method, Cox proportional hazards model.

**Unit 8:**
Statistical Software Applications; Introduction to statistical software packages (e.g., R, SAS, SPSS), Data manipulation and analysis using software tools.

**Unit 9:**
Interpreting and Presenting Statistical Results; Reporting statistical findings, Visualization techniques, Interpreting p-values and confidence intervals.

**Textbooks**

**Course outcome**
CO1: To understand fundamental statistical concepts and their relevance in biomedical research.
CO2: To learn about different types of study designs and their strengths and limitations.
CO3: To acquire skills in data collection, management, and quality assurance.
CO4: To gain proficiency in using statistical software for data analysis.
CO5: To interpret statistical results and communicate findings effectively.

**Program outcome (PO)**

PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.

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Unit 1: Introduction to Ethics in Translational Research, Overview of ethical principles and theories, Historical perspective on research ethics, Importance of ethical considerations in translational research

Unit 2: Ethical Considerations in Study Design and Conduct, Risk-benefit assessment and study feasibility, Selection of study populations and recruitment strategies, Data management and integrity in translational research

Unit 3: Informed Consent and Participant Protection, Elements of informed consent, Capacity to consent and decision-making capacity, Consent issues in vulnerable populations

Unit 4: Ethical Issues in Preclinical Research, Animal welfare and ethical considerations in animal studies, Reduction, refinement, and replacement principles, Translation of preclinical findings to clinical research

Unit 5: Ethical Challenges in Clinical Trials, Randomization and equipoise, Placebo-controlled trials and standard of care, Monitoring and reporting adverse events

Unit 6: Ethical Implications of Emerging Technologies, Gene editing and genetic modification, Stem cell research and regenerative medicine, Artificial intelligence and big data in translational research

Unit 7: Research Integrity and Publication Ethics, Authorship and contributorship, Plagiarism and research misconduct, Peer review and responsible publication practices

Unit 8: Ethical Issues in Translating Research into Practice, Access to investigational therapies, Commercialization and conflicts of interest, Health disparities and global health equity

Unit 9: Basic understanding of GLP, GMP and GCP

Textbooks

Course outcome
CO1: To understand foundational ethical principles and theories relevant to translational research
CO2: To explore ethical considerations in the design, conduct, and dissemination of translational research studies.
CO3: To analyze case studies and real-world examples of ethical challenges in translational research.
CO4: To examine the roles and responsibilities of researchers, institutional review boards (IRBs), and regulatory bodies in ensuring ethical conduct.
CO5: To discuss ethical issues related to informed consent, risk-benefit assessment, and vulnerable populations in translational research.
CO6: To understand the basic quality systems needed for laboratories (GLP), biomanufacturing (GMP) and clinical trial (GCP).
CO7: To develop skills in ethical decision-making and critical thinking through class discussions and assignments.

Program outcome (PO)
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Preamble
Omics in Translational Medicine is a graduate-level course designed to provide students with an advanced understanding of high-throughput omics technologies and their applications in translational medicine. The course will cover genomics, transcriptomics, proteomics, metabolomics, and other omics approaches, with a focus on their integration and utilization in biomedical research and clinical practice. Through lectures, case studies, and hands-on analysis of omics data, students will learn about omics-driven discovery, biomarker identification, personalized medicine, and other translational applications.

Syllabus:
Unit 1:
Introduction to Omics Technologies; Overview of genomics, transcriptomics, proteomics, metabolomics, and other omics approaches, High-throughput sequencing technologies (NGS, RNA-seq, ChIP-seq, etc.), Genomics in Translational Medicine; Genome sequencing and variant analysis, Association studies and genome-wide association studies (GWAS), Pharmacogenomics and personalized medicine

Unit 2:
Transcriptomics and Gene Expression Analysis, Transcriptome profiling techniques (microarrays, RNA-seq), Differential gene expression analysis, Gene co-expression networks and pathway analysis.

Unit 3:
Mass spectrometry-based proteomics and metabolomics, Proteomics and Protein Biomarker Discovery; Mass spectrometry-based proteomics workflows, Identification and validation of protein biomarkers, Clinical applications of proteomics in disease diagnosis and monitoring

Unit 4:
Metabolomics and Metabolic Profiling; Metabolite identification and quantification, Metabolic pathway analysis, Metabolomics in drug metabolism and toxicology, Integrative Omics Approaches; Multi-omics data integration, Systems biology and network analysis, Translational applications of integrated omics approaches. Data Analysis and Bioinformatics Tools; Statistical analysis of omics data, Bioinformatics pipelines for data processing and interpretation, Visualization techniques for omics data analysis.

Unit 5:
Ethical, Legal, and Regulatory Considerations; Data privacy and confidentiality, Informed consent and patient rights, Regulatory pathways for omics-based diagnostics and therapeutics.

Textbooks

Course outcome
CO1: To understand the principles and methodologies of various omics technologies.
CO2: To explore the applications of genomics, transcriptomics, proteomics, and metabolomics in translational medicine.
CO3: To learn about data analysis techniques and bioinformatics tools for omics data interpretation.
CO4: To examine case studies and examples of omics-driven research in disease diagnosis, prognosis, and treatment.
CO5: To discuss ethical, legal, and regulatory considerations related to omics research and clinical implementation.
CO6: To develop practical skills in analyzing and interpreting omics data sets.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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Program Specific Outcome (PSO)
PSO1: Addresses the complexity of interdisciplinary sciences in biological and medical contexts.
PSO2: Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.
PSO3: Covers compounds as drugs and their efficacy, involving pharmacology and drug development.
PSO4: Explores the intersection of bioinformatics and artificial intelligence in biology and medicine.
PSO5: Deals with technology in personalizing medicine, involving precision medicine approaches.
PSO6: Focuses on communicating and disseminating science and medicine to the public, involving science communication and public outreach efforts.

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Preamble
Bioinformatics and Translational Medicine is a graduate-level course that integrates principles from bioinformatics with applications in translational medicine. The course explores how computational techniques can be used to analyse biological data, facilitate biomedical research, and translate discoveries into clinical practice. Topics include genomic analysis, molecular modelling, drug discovery, and personalized medicine. Emphasis is placed on practical skills development and understanding the role of bioinformatics in advancing translational research.

**Syllabus:**

**Unit 1:**
Introduction to Bioinformatics and Translational Medicine; Definition and scope of bioinformatics, Overview of translational medicine.

**Unit 2:**
Biological Databases and Tools; Sequence databases (Gen Bank, Uni Prot), Structure databases (PDB), Bioinformatics software (BLAST, CLUSTALW, etc.).

**Unit 3:**
Genomic Analysis Techniques; Next-generation sequencing (NGS), Genome assembly and annotation, Variant calling and analysis.

**Unit 4:**
Systems Biology and Network Analysis; Gene expression analysis, Pathway analysis, Protein-protein interaction networks.

**Unit 5:**
Molecular Modelling and Drug Design; Protein structure prediction, Molecular docking, Virtual screening for drug discovery.

**Unit 6:**
Personalized Medicine and Precision Oncology; Genomic profiling in cancer, Pharmacogenomics, Clinical applications of personalized medicine.

**Unit 7:**
Computational Tools for Clinical Decision Support; Electronic health records (EHR), Predictive modelling, Biomarker discovery and validation.

**Unit 8:**
Challenges and Future Directions, Data integration and interoperability, Ethical and regulatory considerations, Emerging technologies in bioinformatics and translational medicine.

**Textbooks**
Jake Chen and Maricel Kann, Translational Bioinformatics, PLOS Computational Biology.

**Course outcome**

**CO1:** To understand the principles of bioinformatics and their applications in biomedical research.

**CO2:** To explore bioinformatics tools and databases for analyzing biological data.

**CO3:** To learn about genomic analysis techniques and their relevance to translational medicine.

**CO4:** To investigate computational methods for drug discovery and development.

**CO5:** To discuss the challenges and opportunities in applying bioinformatics to translational research.

**CO6:** To develop practical skills in using bioinformatics software and resources.

**CO7:** To critically evaluate research studies and applications of bioinformatics in translational medicine.

**Program outcome (PO)**

**PO1:** Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

**PO2:** Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

**PO3:** Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
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**Program Specific Outcome (PSO)**

**PSO1:** Addresses the complexity of interdisciplinary sciences in biological and medical contexts.

**PSO2:** Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.

**PSO3:** Covers compounds as drugs and their efficacy, involving pharmacology and drug development.

**PSO4:** Explores the intersection of bioinformatics and artificial intelligence in biology and medicine.

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**24TM507 Laboratory Techniques in Translational Research I 1012**

**Preamble**

Laboratory Techniques in Translational Medical Research is a graduate-level course designed to provide students with hands-on experience in the laboratory techniques commonly used in translational medical research. The course will cover essential laboratory skills, experimental design, data analysis, and interpretation relevant to translational research in medicine. Through laboratory sessions, demonstrations, lectures, and practical exercises, students will gain
proficiency in various molecular, cellular, and biochemical techniques essential for conducting translational research.

**Syllabus:**

**Unit 1:**
Introduction to Laboratory Techniques in Translational Research, Overview of translational medical research, Importance of laboratory techniques in translational research, Laboratory safety practices and regulations

**Unit 2:**
Basic Laboratory Skills and Equipment Operation, Laboratory pipetting techniques, Measurement and calibration of laboratory equipment, Use of laboratory instruments (centrifuges, spectrophotometers, etc.)

**Unit 3:**
Molecular Biology Techniques, DNA/RNA extraction and purification methods, Polymerase chain reaction (PCR) and real-time PCR, Gene cloning and recombinant DNA technology

**Unit 4:**
Cell Culture Techniques, Cell line maintenance and culture, Primary cell isolation and culture, Cell proliferation, viability, and assays

**Textbooks**

**Course outcome**

**CO1:** To acquire proficiency in a variety of laboratory techniques commonly used in translational medical research.

**CO2:** To understand the principles underlying each laboratory technique, including experimental design, data analysis, and interpretation.

**CO3:** To learn about the application of laboratory techniques in studying disease mechanisms, biomarker discovery, and therapeutic development.

**CO4:** To develop critical thinking skills in experimental design, troubleshooting, and result interpretation.

**CO5:** To gain hands-on experience in laboratory safety practices, equipment operation, and data documentation.

**CO6:** To apply laboratory techniques to address specific research questions relevant to translational medicine.

**Program outcome (PO)**

**PO1:** Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

**PO2:** Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

**PO3:** Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.

**PO4:** Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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Course Objectives

The course will enable the students to

- Mastery Over Mind (MAOM) is an Amrita initiative to implement schemes and organize university-wide programs to enhance health and wellbeing of all faculty, staff, and students (UN SDG -3)
- It gives an introduction to immediate and long-term benefits of MA OM meditation and equips every attendee to manage stressful emotions and anxiety, in turn facilitating inner peace and harmony.
- This course will enhance the understanding of experiential learning based on the University’s mission: “Education for Life along with Education for Living” and is aimed to allow learners to realize and rediscover the infinite potential of one’s true Being and the fulfilment of life’s goals.

Course Outcomes

CO1: To be able to describe what meditation is and to understand its health benefits
CO2: To understand the causes of stress and how meditation improves well-being
CO3: To understand the science of meditation
CO4: To learn and practice MAOM meditation in daily life

CO5: To understand the application of meditation to improve communication and relationships

CO6: To be able to understand the power of meditation in compassion-driven action

CO-PO Mapping

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Syllabus:

**Unit 1: Describe Meditation and Understand its Benefits (CO1)**
A: Importance of meditation. How does meditation help to overcome obstacles in life *(Pre-recorded video with Swami Shubhamritananda Puri)*
Reading 1: Why Meditate? (Swami Shubamritananda ji)

**Unit 2: Causes of Stress and How Meditation Improves Well-being (CO2)**
A: Learn how to prepare for meditation. Understand the aids that can help in effectively practicing meditation. Understand the role of sleep, physical activity, and a balanced diet in supporting meditation. *(Pre-recorded video with Dr. Ram Manohar)*

**Unit 3: The Science of Meditation (CO3)**
A: A preliminary understanding of the Science of meditation. What can modern science tell us about this tradition-based method? *(Pre-recorded video with Dr. Shyam Diwakar)*
B: How meditation helps humanity according to what we know from scientific research *(Pre-recorded video with Dr. Shyam Diwakar)*
Reading 1: Does Meditation Aid Brain and Mental Health (Dr Shyam Diwakar)

Unit 4: Practicing MA OM Meditation in Daily Life (CO4)
Guided Meditation Sessions following scripts provided (Level One to Level Five)
Reading 1: MA OM and White Flower Meditation: A Brief Note (Swami Atmananda Puri)

Unit 5: Improving Communication and Relationships (CO5)
How meditation and mindfulness influence interpersonal communication. The role of meditation in improving relationship quality in the family, at the university and in the workplace. (Pre-recorded video with Dr Shobhana Madhavan)

Unit 6 Meditation and Compassion-driven Action (CO6)
Understand how meditation can help to motivate compassion-driven action. (Pre-recorded video with Dr Shobhana Madhavan)

Text Books/Reference Books:
1. Meditation and Spiritual Life-Swami Yatiswarananda, Ramakrishna Math
3. Dhyana Yoga-Holy Gita Swami Chinmayanda
4. Voice of God, Chandrasekharendra Saraswati, 68th Acharya of Sri Kanchi Kamakoti Peetam,
5. Hindu Dharma-Chandrasekharendra Saraswati, 68th Acharya of Sri Kanchi Kamakoti Peetam,
6. Mind: It’s Mysteries and control-Swami Sivananda Saraswati
8. Books on Amma’s teachings like Awaken children, From Amma’s Heart etc.
11. Seppala E (2022, June 30th) 5 Unexpected Ways Meditation Improves Relationships a Lot. Psychology Today

Evaluation Pattern
Second Semester

24TM511  Entrepreneurship in Biomedical Sciences  3 0 0 3

Preamble
Entrepreneurship in Biomedical Sciences is a graduate-level course designed to provide students with the knowledge and skills necessary to translate biomedical innovations into successful ventures. The course will cover topics such as identifying opportunities, developing business models, securing funding, navigating regulatory pathways, and commercializing biomedical technologies. Through lectures, case studies, guest speakers, and hands-on exercises, students will learn about the entrepreneurial ecosystem in the biomedical field and develop strategies for launching and managing biomedical startups.

Syllabus:
Unit 1:
Introduction to Entrepreneurship in Biomedical Sciences, Overview of the entrepreneurial ecosystem, Role of entrepreneurship in translating biomedical research into products and services, Introduction to business model canvas and lean startup methodology

Unit 2:
Identifying Opportunities in Biomedical Innovation, Trends and opportunities in biomedical research and healthcare, Needs assessment and market analysis, Identifying unmet clinical needs and customer pain points

Unit 3:
Business Planning and Strategy Development, Business model development and validation, Strategic planning and competitive analysis, Value proposition design and customer segmentation

Unit 4:
Intellectual Property Management and Technology Transfer, Basics of intellectual property (IP) protection, Patenting process and strategies for IP management, Licensing agreements and technology transfer in academia-industry partnerships

Unit 5:
Funding and Financing in Biomedical Entrepreneurship, Sources of funding for biomedical startups (grants, angel investors, venture capital), Pitching and fundraising strategies, Financial modeling and valuation techniques

Unit 6:
Regulatory Affairs and Compliance in Biomedical Ventures, Overview of regulatory pathways for medical devices, diagnostics, and therapeutics, Compliance with FDA regulations and other regulatory agencies, Quality management systems and Good Manufacturing Practices (GMP)

Unit 7:
Case Studies of Successful Biomedical Startups, Analysis of successful entrepreneurial ventures in biotechnology, medical devices, and digital health, Lessons learned from real-world examples of biomedical innovation and commercialization

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• CA – Can be Quizzes, Assignment, Projects, and Reports
Unit 8:
Developing a Business Plan and Pitch Presentation, Components of a business plan (executive summary, market analysis, financial projections, etc.), Pitch deck essentials and effective communication strategies, Peer review and feedback on business plan presentations

Textbooks

Course outcome
CO1: To understand the principles and processes of entrepreneurship in the biomedical sciences.
CO2: To identify opportunities for innovation and commercialization in biomedical research.
CO3: To develop skills in business planning, market analysis, and intellectual property management.
CO4: To learn about funding sources, investment strategies, and venture capital in the biomedical sector.
CO5: To explore regulatory pathways and compliance requirements for biomedical products and services.
CO6: To analyze case studies of successful biomedical startups and entrepreneurial ventures.
CO7: To develop a business plan or pitch presentation for a biomedical startup concept.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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Program Specific Outcome (PSO)
PSO1: Addresses the complexity of interdisciplinary sciences in biological and medical contexts.
PSO2: Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.
PSO3: Covers compounds as drugs and their efficacy, involving pharmacology and drug development.
PSO4: Explores the intersection of bioinformatics and artificial intelligence in biology and medicine.
PSO5: Deals with technology in personalizing medicine, involving precision medicine approaches.
PSO6: Focuses on communicating and disseminating science and medicine to the public, involving science communication and public outreach efforts.

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Preamble
Artificial Intelligence (AI) in Medicine is a graduate-level course designed to provide students with an advanced understanding of how AI and machine learning techniques are transforming healthcare delivery, clinical decision-making, and biomedical research. The course will cover topics such as machine learning algorithms, deep learning architectures, natural language processing, and computer vision, with a focus on their applications in medical imaging, diagnostics, patient management, and personalized medicine. Through lectures, case studies, hands-on exercises, and guest speakers, students will explore the opportunities and challenges of integrating AI into healthcare systems.

Syllabus:
Unit 1:
Introduction to Artificial Intelligence in Medicine, Definition and scope of AI in healthcare, Historical perspective and milestones in AI research, Applications of AI in clinical practice and biomedical research

Unit 2:
Fundamentals of Machine Learning, Supervised, unsupervised, and reinforcement learning, Feature engineering and model evaluation, Bias-variance tradeoff and model interpretability

Unit 3:
Deep Learning Architectures, Neural networks, convolutional neural networks (CNNs), and recurrent neural networks (RNNs), Deep learning frameworks (e.g., TensorFlow, PyTorch), Transfer learning and pre-trained models

Unit 4:
AI in Medical Imaging, Image classification, segmentation, and registration, Radiomics and quantitative imaging biomarkers, Applications of AI in radiology, pathology, and ophthalmology

Unit 5:
AI in Diagnostics and Disease Prediction, Predictive modeling for disease risk assessment, Diagnostic decision support systems, Early detection of diseases using AI algorithms

Unit 6:
Natural Language Processing (NLP) in Healthcare, Text mining and information extraction from clinical notes, Clinical language understanding and medical coding, Applications of NLP in electronic health records (EHR) analysis and clinical documentation

Unit 7: AI in Personalized Medicine and Treatment Planning, Pharmacogenomics and precision medicine, Treatment recommendation systems, Drug discovery and repurposing using AI approaches

Unit 8: Ethical, Legal, and Social Implications (ELSI) of AI in Medicine, Bias and fairness in AI algorithms, Privacy and security of healthcare data, Regulation and policy considerations for AI in healthcare


Course outcome
CO1: To understand the fundamentals of artificial intelligence and machine learning and their applications in medicine.
CO2: To explore advanced AI techniques, including deep learning, reinforcement learning, and natural language processing.
CO3: To learn about the use of AI in medical imaging, diagnostics, disease prediction, and treatment planning.
CO4: To examine the ethical, legal, and social implications of AI in medicine, including issues of bias, privacy, and equity.
CO5: To gain hands-on experience with AI tools and platforms through practical exercises and projects.
CO6: To critically evaluate research studies and applications of AI in healthcare.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
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Program Specific Outcome (PSO)
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PSO3: Covers compounds as drugs and their efficacy, involving pharmacology and drug development.

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24TM581 Clinical Observation and Patient Interaction 0 0 1 1

Preamble
Clinical Observation of Patient Care and Treatment Procedures is a graduate-level course designed to provide students with the opportunity to observe various aspects of patient care and medical procedures in clinical settings. Through direct observation, students will gain insights into the delivery of healthcare services, interdisciplinary collaboration, and patient-provider interactions. The course will focus on understanding the roles of healthcare professionals, patient safety protocols, and ethical considerations in clinical practice. Through structured observations, reflective exercises, and discussions, students will develop a deeper understanding of healthcare delivery and enhance their clinical observational skills.

Syllabus:

Unit 1: Introduction to Clinical Observation and Healthcare Settings, Overview of course objectives and expectations, Introduction to healthcare settings (hospitals, clinics, long-term care facilities), Roles and responsibilities of healthcare professionals

Unit 2: Patient Care and Interdisciplinary Collaboration, Observation of patient assessments and care delivery, Interactions between healthcare providers and patients/families, Collaboration among healthcare team members (physicians, nurses, allied health professionals)

Unit 3: Medical Procedures and Treatment Modalities, Observation of medical procedures (e.g., injections, wound care, vital signs monitoring), Introduction to diagnostic tests and imaging procedures, Review of common treatment modalities (medications, therapies, interventions)

Unit 4: Patient Safety and Infection Control, Understanding of patient safety protocols and procedures, Observation of infection control measures (hand hygiene, personal protective equipment), Identification and reporting of safety hazards in clinical settings

Unit 5:
Ethical Considerations and Cultural Competence, Ethical principles in healthcare delivery (autonomy, beneficence, non-maleficence), Cultural competence and sensitivity to patient diversity, Confidentiality, privacy, and informed consent in clinical practice

Unit 6: Regulatory Requirements and Quality Improvement, Overview of healthcare regulations and standards (HIPAA, JCAHO, OSHA), Quality improvement initiatives and patient outcomes measurement, Role of accreditation and certification bodies in healthcare

Unit 7: Reflection and Professional Development, Reflective exercises on clinical observations and experiences, Discussion of ethical dilemmas and challenging situations encountered during observations, Professional development opportunities and resources in healthcare

Unit 8: Final Reflection and Integration, Synthesis of learning from clinical observations and discussions, Identification of personal learning goals and areas for further development, Development of a reflective portfolio or final project summarizing key insights and experiences

Textbooks

Course outcome
CO1: To provide students with opportunities to observe patient care and treatment procedures in clinical settings.
CO2: To familiarize students with the roles and responsibilities of healthcare professionals involved in patient care.
CO3: To develop observational skills for assessing patient interactions, communication, and clinical procedures.
CO4: To understand patient safety protocols, infection control measures, and regulatory requirements in healthcare settings.
CO5: To explore ethical considerations, cultural competence, and professionalism in clinical practice.
CO6: To promote reflection and critical thinking about healthcare delivery and patient experiences.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
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24TM513 Precision and Translational Medicine 2002

Preamble

Precision and Translational Medicine is a graduate-level course designed to provide students with an in-depth understanding of the principles, methodologies, and applications of precision medicine in translational research and clinical practice. The course will cover topics such as molecular diagnostics, personalized therapies, biomarker discovery, and implementation strategies. Through lectures, case studies, and hands-on activities, students will explore the interdisciplinary nature of precision medicine and its potential to revolutionize healthcare.

Syllabus:

Unit 1:
Introduction to Precision and Translational Medicine; Definition and principles of precision medicine, Overview of translational research continuum, Role of precision medicine in improving patient outcomes.

Unit 2:
Molecular Diagnostics and Genetic Testing; Techniques for DNA and RNA analysis, Next-generation sequencing technologies, Clinical applications of genetic testing in precision medicine

Unit 3:
Personalized Therapies and Targeted Treatment Approaches, Pharmacogenomics and individualized drug responses. Targeted therapies for cancer and other diseases; Immunotherapy and precision oncology

Unit 4:
Biomarker Discovery and Validation; Biomarker identification strategies, Validation methods for biomarker candidates, Clinical utility and implementation of biomarkers in precision medicine.

Unit 5:
Data Integration and Computational Approaches; Big data analytics in precision medicine, Machine learning and predictive modeling, Data integration platforms and resources.

Unit 6:
Implementation Strategies for Precision Medicine; Challenges in integrating precision medicine into healthcare systems, Ethical, legal, and social implications (ELSI) of precision medicine, Regulatory considerations and policy frameworks.

Unit 7:
Case Studies in Precision Medicine; Precision medicine initiatives and consortia, Success stories and lessons learned from precision medicine projects, Patient-centric approaches and patient engagement in precision medicine research.

Unit 8:
Future Directions and Emerging Technologies; Advancements in omics technologies, Integration of artificial intelligence and digital health in precision medicine, Global perspectives on precision medicine initiatives.

Textbooks

Course outcome
CO1: To understand the principles and concepts of precision medicine and translational research.
CO2: To explore molecular diagnostics techniques and their applications in precision medicine.
CO3: To learn about personalized therapies and targeted treatment approaches.
CO4: To examine strategies for biomarker discovery and validation in precision medicine.
CO5: To discuss the challenges and opportunities in implementing precision medicine in clinical practice.
CO6: To analyze case studies and real-world examples of precision medicine applications.
CO7: To develop critical thinking and problem-solving skills in the context of precision and translational medicine.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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Program Specific Outcome (PSO)

**PSO1:** Addresses the complexity of interdisciplinary sciences in biological and medical contexts.

**PSO2:** Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.

**PSO3:** Covers compounds as drugs and their efficacy, involving pharmacology and drug development.

**PSO4:** Explores the intersection of bioinformatics and artificial intelligence in biology and medicine.

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**24TM514**  
**Translational Neuroscience**  
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**Preamble**

Translational Neuroscience is a graduate-level course designed to provide students with an in-depth understanding of the principles, methodologies, and applications of neuroscience research in translational medicine. The course will cover advanced topics in neuroscience, including neural circuitry, neuropharmacology, neuroimaging, and neurogenetics, with a focus on translating basic research findings into clinical applications. Through lectures, seminars, case studies, and hands-on activities, students will explore the interface between basic neuroscience research and clinical practice.

**Syllabus:**

**Unit 1:**
Introduction to Translational Neuroscience, Definition and scope of translational neuroscience, Historical perspective and milestones in the field, Importance of interdisciplinary collaboration

**Unit 2:**
Neural Circuitry and Systems Neuroscience, Structure and function of neural circuits, Neurotransmission and synaptic plasticity, Neural circuits underlying behavior and cognition

**Unit 3:**
Neuropharmacology and Drug Development, Mechanisms of drug action in the nervous system, Pharmacotherapy for neurological and psychiatric disorders, Drug discovery and development process

**Unit 4:**
Neurogenetics and Genomic Medicine, Genetic basis of neurological and psychiatric disorders, Advances in genomics and personalized medicine, Gene therapy and gene editing approaches

Unit 5:
Neuroimaging Techniques and Applications, Structural and functional neuroimaging modalities, Applications of neuroimaging in translational neuroscience, Imaging biomarkers for disease diagnosis and monitoring

Unit 6:
Animal Models in Translational Neuroscience, Use of animal models in neuroscience research, Challenges and limitations of animal models, Translation of preclinical findings to clinical practice

Unit 7:
Translational Approaches to Neurological Disorders, Stroke and neurodegenerative diseases, Traumatic brain injury and spinal cord injury, Psychiatric disorders and addiction

Unit 8:
Ethical, Legal, and Social Implications (ELSI) of Translational Neuroscience, Informed consent and ethical considerations in neuroscience research, Neuroethics and implications of emerging technologies, Policy and regulatory frameworks in translational neuroscience

Textbooks

Course outcome
CO1: To understand the principles of translational neuroscience and its significance in bridging the gap between basic research and clinical applications.
CO2: To explore advanced topics in neuroscience, including neural circuitry, neuropharmacology, and neurogenetics.
CO3: To learn about cutting-edge techniques and methodologies in neuroimaging and functional neuroscience.
CO4: To examine the role of translational neuroscience in the diagnosis, treatment, and prevention of neurological and psychiatric disorders.
CO5: To analyze case studies and research articles to understand the translational potential of neuroscience research.
CO6: To develop critical thinking skills in evaluating the efficacy, safety, and ethical implications of translational neuroscience interventions.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
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Program Specific Outcome (PSO)

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**PSO2**: Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.

**PSO3**: Covers compounds as drugs and their efficacy, involving pharmacology and drug development.

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Unit 4:
Neuropharmacology, Neurotransmitter systems and synaptic transmission, Mechanisms of action of psychoactive drugs, Pharmacotherapy for neurological and psychiatric disorders

Unit 5:
Cardiovascular Pharmacology, Regulation of blood pressure and cardiac function, Antiarrhythmic drugs and treatment of heart failure, Pharmacotherapy for cardiovascular diseases

Unit 6:
Anti-Infective Pharmacology, Antibiotics: mechanisms of action and resistance, Antiviral and antifungal agents, Treatment of microbial infections and emerging infectious diseases

Unit 7:
Oncology Pharmacology, Mechanisms of carcinogenesis and tumor growth, chemotherapeutic agents and targeted therapies, personalized medicine approaches in oncology

Unit 8:
Immunopharmacology and Inflammation, Immunomodulatory drugs and biological therapies, Anti-inflammatory agents and treatment of autoimmune diseases, Vaccines and immunization strategies

Textbooks
Teferra Abula, Srinivasa A.Rao, Amare Mengistu, Solomomon Worku, Eshetu Legesse, Musie Aberra, Pharmacology, University of Gondar

Course outcome
CO1: To understand advanced concepts in pharmacodynamics and pharmacokinetics.
CO2: To explore the molecular mechanisms of drug action and drug-receptor interactions.
CO3: To learn about drug metabolism, pharmacogenomics, and personalized medicine.
CO4: To examine the therapeutic applications of drugs in major disease areas.
CO5: To analyze case studies and research articles to understand the rational design of pharmacotherapies.
CO6: To develop critical thinking skills in evaluating the efficacy, safety, and pharmacological profiles of drugs.

Program outcome (PO)
PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.
PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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24TM516 Clinical Trials and Regulatory Affairs 3 0 0 3

Preamble
Clinical Trials and Regulatory Affairs is a graduate-level course designed to provide students with a comprehensive understanding of the principles, methodologies, regulations, and ethical considerations involved in the conduct of clinical trials and the regulatory approval process for pharmaceuticals, biologics, and medical devices. The requirement of preclinical validation before clinical trial will be explained. The course will cover key topics such as trial design, participant recruitment, data management, regulatory submissions, and post-market surveillance.

Syllabus:
Unit 1:
Introduction to Clinical Trials; Definition and objectives, Historical perspective; Ethical principles and guidelines, Requirement of preclinical validation.

Unit 2:

Unit 3:
Clinical Trial Design; Randomization and blinding, Sample size determination, Endpoint selection and measurement.

Unit 4:
Participant Recruitment and Informed Consent, Strategies for participant recruitment, Informed consent process and documentation, Vulnerable populations and special considerations.

Unit 5:
Data Management and Quality Assurance, Electronic data capture systems, Data monitoring and auditing, Good Clinical Practice (GCP) guidelines.

**Unit 6:**
Regulatory Requirements and Submissions; FDA & CDSO regulations and guidance documents, Investigational New Drug (IND) application, Investigational Device Exemption (IDE) application.

**Unit 7:**
Ethics in Clinical Research; Institutional Review Board (IRB) review process, Protection of human subjects, Adverse event reporting and safety monitoring.

**Unit 8:**
Post-Market Surveillance and Compliance; Pharmacovigilance and adverse event reporting Risk management plans, Regulatory inspections and audits.

**Textbooks**

**Course outcome**
**CO1:** To understand the purpose and significance of clinical trials in drug development and medical device evaluation.
**CO2:** To learn about different phases of clinical trials and their design considerations.
**CO3:** To acquire knowledge of regulatory requirements and guidelines governing clinical research and preclinical validation.
**CO4:** To develop skills in protocol development, study management, and data analysis.
**CO5:** To explore ethical considerations and patient safety in clinical trials.
**CO6:** To gain insights into post-market surveillance and regulatory compliance.

**Program outcome (PO)**
**PO1:** Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.
**PO2:** Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.
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24TM517 Laboratory Techniques in Translational Research II 1012

**Preamble**

Laboratory Techniques in Translational Medical Research is a graduate-level course designed to provide students with hands-on experience in the laboratory techniques commonly used in translational medical research. The course will cover essential laboratory skills, experimental design, data analysis, and interpretation relevant to translational research in medicine. Through laboratory sessions, demonstrations, lectures, and practical exercises, students will gain proficiency in various molecular, cellular, and biochemical techniques essential for conducting translational research.

**Syllabus:**

**Unit 1:**
Protein Techniques, Protein extraction and purification methods, SDS-PAGE and western blotting, Enzyme-linked immunosorbent assay (ELISA)

**Unit 2:**
Immunohistochemistry and Immunofluorescence, Tissue fixation and processing, Antibody staining and detection, Microscopy and image analysis

**Unit 3:**
Flow Cytometry and Cell Sorting, Principles of flow cytometry, Fluorescent labelling and analysis of cells, Cell sorting techniques

**Textbooks**


**Course outcome**

**CO1**: To acquire proficiency in a variety of laboratory techniques commonly used in translational medical research.
CO2: To understand the principles underlying each laboratory technique, including experimental design, data analysis, and interpretation.

CO3: To learn about the application of laboratory techniques in studying disease mechanisms, biomarker discovery, and therapeutic development.

CO4: To develop critical thinking skills in experimental design, troubleshooting, and result interpretation.

CO5: To gain hands-on experience in laboratory safety practices, equipment operation, and data documentation.

CO6: To apply laboratory techniques to address specific research questions relevant to translational medicine.

Program outcome (PO)

PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

PO3: Engage in ethical conduct, leadership, active listening, constructive feedback, and interpersonal communication to facilitate productive collaborations and knowledge exchange.

PO4: Acquire fundamental and advanced knowledge and skills in project management, financial planning, and entrepreneurship relevant to translational research ventures and initiatives.

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Program Specific Outcome (PSO)

PSO1: Addresses the complexity of interdisciplinary sciences in biological and medical contexts.

PSO2: Deals with regulatory affairs in medicine, covering topics such as ethical considerations and regulatory frameworks.

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1. Orientation and Project Proposal Development
   Introduction to the capstone project requirements and expectations
   Overview of research methodologies and study design in translational medicine
   Guidance on selecting a research topic, formulating research questions, and developing a project proposal
   Initial meetings with faculty mentors to discuss project ideas and proposal development
2. Literature Review and Background Research
   Conducting a comprehensive review of relevant literature and research studies
   Identifying gaps in current knowledge and understanding in the chosen research area
   Developing a theoretical framework and rationale for the proposed research project
   Drafting the literature review section of the capstone project proposal
3. Research Design and Methodology
   Refinement of research questions and hypotheses based on literature review findings
   Selection of appropriate research methods, study design, and data collection techniques
   Development of a detailed research plan, including study protocol, data collection instruments, and ethical considerations
   Drafting the research design and methodology sections of the capstone project proposal
4. Data Collection and Analysis
   Implementation of the research plan and data collection procedures
   Quality assurance and data validation processes
   Data analysis using appropriate statistical methods and software
   Interpretation of research findings and preliminary conclusions
5. Results Presentation and Discussion
   Preparation of a written report summarizing research findings, methods, and implications
   Development of visual aids (e.g., tables, figures, graphs) to illustrate key results
   Practice sessions for oral presentations of research findings to peers and faculty
   Peer review and feedback on draft capstone project reports and presentations
6. Finalization and Submission
   Revision and finalization of the capstone project report based on feedback received
   Preparation of a final presentation summarizing research findings and conclusions
   Submission of the completed capstone project report and presentation materials
   Presentation of capstone projects to peers, faculty, and invited guests during a culminating event

Course outcome
CO1: To demonstrate proficiency in designing, conducting, and analyzing research in the field of translational medicine.
CO2: To apply knowledge and skills acquired in coursework to address a specific translational medicine question or problem.
CO3: To engage in critical thinking and problem-solving within the context of translational medicine research.
CO4: To demonstrate effective communication of research findings through written and oral presentations.
CO5: To collaborate with peers, faculty, and external stakeholders to advance knowledge and understanding in translational medicine.
To adhere to ethical standards and principles in the conduct of research and dissemination of findings.

Program outcome (PO)

PO1: Utilize scientific principles and methodologies to design innovative solutions for data analysis, experimentation, and product development for challenges in translational research.

PO2: Recognize the importance of environmental sustainability in translational research and strive to minimize adverse environmental impacts.

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