Estd. 1962
"A++" Accredited by
NAAC (2021)
With CGPA 3.52

SHIVAJI UNIVERSITY, KOLHAPUR - 416004, MAHARASHTRA

PHONE:EPABX-2609000, www.unishivaji.ac.in, bos@unishivaji.ac.in

शिवाजी विद्यापीठ, कोल्हापूर -४१६००४,महाराष्ट्र

दूरध्वनी-ईपीएबीएक्स -२६०९०००, अभ्यासमंडळे विभाग दुरध्वनी ०२३१—२६०९०९४
०२३१—२६०९४८७

SU/BOS/Science/09 **Date: 02/01/2024**

To,

The Principal, All Concerned Affiliated Colleges/Institutions Shivaji University, Kolhapur	The Head/Co-ordinator/Director All Concerned Department (Science) Shivaji University, Kolhapur.

Subject: Regarding syllabi of M.Sc. Part-II (Sem. III & IV) as per NEP-2020 (1.0) degree programme under the Faculty of Science and Technology.

Sir/Madam,

With reference to the subject mentioned above, I am directed to inform you that the university authorities have accepted and granted approval to the revised syllabi, nature of question paper and equivalence of M.Sc. Part-II (Sem. III & IV) as per NEP-2020 (1.0) degree programme under the Faculty of Science and Technology.

M.Sc.Part-II (Sem. III & IV) as per NEP-2020 (1.0)			
1.	Computer Science	7.	Biochemistry (HM)
2.	Data Science	8.	Biotechnology (HM)
3.	Information Technology (Entire)	9.	Biotechnology
4.	M.C.A.	10.	Medical Information Management
5.	Food Science & Nutrition	11.	Environmental Science
6	Food Science & Technology	12.	

This syllabus, nature of question and equivalence shall be implemented from the academic year 2024-2025 onwards. A soft copy containing the syllabus is attached herewith and it is also available on university website www.unishivaji.ac.in NEP-2020 (Online Syllabus)

The question papers on the pre-revised syllabi of above-mentioned course will be set for the examinations to be held in October /November 2024 & March/April 2025. These chances are available for repeater students, if any.

You are, therefore, requested to bring this to the notice of all students and teachers concerned.

Thanking you,

Dy Registrar
Dr. S. M. Kubal

Copy to:

1	The Dean, Faculty of Science & Technology	8	P.G. Admission/Seminar Section
2	Director, Board of Examinations and Evaluation	9	Computer Centre/ Eligibility Section
3	The Chairman, Respective Board of Studies	10	Affiliation Section (U.G.) (P.G.)
4	B.Sc. Exam/ Appointment Section	11	Centre for Distance Education

SHIVAJI UNIVERSITY, KOLHAPUR

Established: 1962

A^{++} Accredited by NAAC (2021) with CGPA 3.52
Structure and Syllabus in Accordance with

National Education Policy - 2020

with Multiple Entry and Multiple Exit

Master of Science (Medical Information Management)

under
Faculty of Science and Technology

(To Be Implemented from Academic Year 2023-24)

INDEX

M. Sc. II: Medical Information Management (NEP)

Department of Biochemistry,

SHIVAJI UNIVERSITY, KOLHAPUR

In collaboration with

Hochschule Hannover – University of AppliedSciences and Arts, Germany

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1. Preamble

In the recent years in this age of Internet and information technology, we have more information at our fingertips than ever before. Organizing this entire data and combating information overload is becoming more and more important. It is thus necessary for institutes like university to evolve a system, which is most accurate and more student friendly. Keeping this view in mind we have decided to start a master programme in Medical Information Management in collaboration with Hochschule Hannover – University of Applied Sciences and Arts, Germany. After completion of this two year M.Sc. course students can be accommodated in any national/multinational drug designing pharmaceutical company, academia as well as in Clinical Research Organizations (CROs).

Advances in biosciences, clinical medicine and medical technologies have enabled increasing personalized health care. The digitization of healthcare information facilitates new connections, insights and transparency. These developments will include medical information management in educational course format in the coming years and decades. Demographic change is leading to an increasing number of chronically ill and multimorbid patients. This would lead to an increasing need for information management. The years of delays in the introduction a nationwide telematic infrastructure and an electronic health card, as well as the delays in establishing a cross-sectoral quality assurance of health care show problem areas of modern medical information management. The advances in various interdisciplinary areas of bioscience, clinical medicine and medical technology indicate an increasing need for clinical trials to progress and to make patients accessible. The value of clinical trials is not just to contribute to the development of new therapies but to take proper care of patients. For many participants it means a new drug/option they will be treated with as part of a study.

Clinical research includes planning, implementation, evaluation and publicationof clinical trials. In this context, special knowledge is necessary about legal requirementsat national and international level as well as all other related issues such as collaboration with institutions of higher education, centers of excellence and authorities, aspects of security of subjects / patients in clinical trials, patient information, insurance and ethical issues. For reimbursement of medicinal products, pharmaco economic data are required, that collection and analysis needs special training. Relevant aspects of benefit for patients such as adequate surrogate parameters and quality of life data require specific recording tools as well as rating benefits that are becoming increasingly important for clinical research and require specialized trained staff.

Medical Information Management course would be useful to train our students in rapidly developing and emerging areas of biosciences, clinical medicine, health sciences, health policy, IPR related activities, drug discovery and designing. These experts are continuously required in various clinical and pharmaceutical industries.

2. **Duration**

Two-Year full-time course with Four semesters

Intake capacity: 20 students per year

3. Eligibility for Admission:

A candidate possessing B.Sc. degree in Science (Chemistry/ Physics/ Electronics/ Nanoscience and Technology/ Statistics/ Mathematics/ Biochemistry/ Biotechnology/ Microbiology /Bioinformatics/ Botany/ Zoology / Nursing / Computer Sciences/ Life Sciences/ Agriculture Sciences/ Veterinary Sciences);/ B.Pharm./B.E./B.Tech./B.A.M.S./B.H.M.S./B.D.S./M.B.B.S.) who have passed the entrance examination conducted by the Shivaji University, Kolhapur shall be held eligible for admission to M.Sc. in Medical Information Management course. Students from other Universities with above mentioned degrees and who have passed the entrance examination conducted by the University are also eligible.

4. Student/Faculty Exchange: Students and faculty exchange will be done as per MoU, which will be signed between Shivaji University, Kolhapur, Maharashtra, and Hochschule Hannover – University of Applied Sciences and Arts, Germany.

- **Program Structure:** Two year duration; Syllabus structure as per NEP along with research project (Master Thesis).

<table>
<tr><td>University</td><td>Sept – Jan.</td><td>Feb.- July</td><td>Sept – Jan</td><td>March-July</td></tr>
<tr><td>Shivaji University, Kolhapur
(Two Year duration)</td><td>Sem I</td><td>Sem II</td><td>Sem III</td><td>Sem IV (Project)
(Student Exchange)</td></tr>
<tr><td></td><td></td><td colspan="3">Common syllabus</td></tr>
<tr><td>Hocshule Hannover University, Germany</td><td>-</td><td>Sem I</td><td>Sem II</td><td>Sem III (Project)
(Student Exchange)</td></tr>
</table>

- **Exam Pattern:** NEP, Semester Pattern (80 External/20 Internal evaluations).
- This course is as per new M.Sc. NEP pattern
- All rules of new M.Sc. NEP pattern will be applicable for this course.

5. Program Structure:

Structure in Accordance with National Education Policy - 2020
With Multiple Entry and Multiple Exit Options
M.Sc. (Medical Information Management) Part – I (Level-6.0)

	Course Code	Teaching Scheme			Examination Scheme					
		Theory and Practical			University Assessment (UA)			Internal Assessment (IA)		
		Lectures (Hours / week)	Practical (Hours / week)	Credit	Maximum Marks	Minimum Marks	Exam. Hours	Maximum Marks	Minimum Marks	Exam. Hours
Semester-I										
Major Mandatory Theory	MMI 101	4	--	4	80	32	3	20	8	0.5
	MMI 102	4	--	4	80	32	3	20	8	0.5
Major Elective Theory	E-MMI 103A **OR** E-MMI 103 B	4	--	4	80	32	3	20	8	0.5
Major Mandatory Practical	P-MMI 104	--	8	4	100	40	12	--	--	--
	P-MMI 105	--	4	2	50	20	6	--	--	--
Research Methodology	RM-MMI 106	4	--	4	80	32	3	20	8	0.5
Total				22	470			80		
Semester-II										
Major Mandatory Theory	MMI 201	4	--	4	80	32	3	20	8	0.5
	MMI 202	4	--	4	80	32	3	20	8	0.5
Major Elective Theory	E-MMI 203	4	--	4	80	32	3	20	8	0.5
Major Mandatory Practical	P-MMI 204	--	8	4	100	40	12	--	--	--
	P-MMI 205	--	4	2	50	20	6	--	--	--
OJT/FP	OJT-MMI 206 **OR** FP-MMI 206	--	--	4	--	--	--	100	40	*
Total				22	390			160		
Total (Sem I + Sem II)				44	860			240		

<table>
<tr><td>• MMI – Major Mandatory Theory
• P-MMI – Major Mandatory Practical
• E-MMI – Major Elective Theory
• RM -MMI - Research Methodology
• OJT-MMI /FP-MMI - On Job Training/ Field Project</td><td>• Total Marks for M.Sc.-I: 1100
• Total Credits for M.Sc.-I (Semester I & II): 44
• Separate passing is mandatory for University and Internal Examinations</td></tr>
<tr><td colspan="2">*Evaluation scheme for OJT/FP shall be decided by concerned BOS</td></tr>
<tr><td colspan="2">Requirement for Entry at Level 6.0:
B. Sc in Science (Chemistry/ Physics/ Electronics/ Nanoscience and Technology/ Statistics/ Mathematics/ Biochemistry/ Biotechnology/ Microbiology /Bioinformatics/ Botany/ Zoology / Nursing / Computer Sciences/ Life Sciences/ Agriculture Sciences/ Veterinary Sciences);/ B.Pharm./B.E./B.Tech./B.A.M.S./B.H.M.S./B.D.S./M.B.B.S.) and appeared for entrance examination (as per eligibility).</td></tr>
<tr><td colspan="2">Requirement for Exit after Level 6.0:
Students can exit after completion of Level 6.0 (44 Credits) with Post Graduate Diploma in Medical Information Management</td></tr>
<tr><td colspan="2">Requirement for Entry at Level 6.5:
Completion of Level 6.0</td></tr>
</table>

Structure in Accordance with National Education Policy - 2020
With Multiple Entry and Multiple Exit Options
M.Sc. (Medical Information Management) Part – II (Level-6.5)

	Course Code	Teaching Scheme			Examination Scheme					
		Theory and Practical			University Assessment (UA)			Internal Assessment (IA)		
		Lectures Hours (Per week)	Practical Hours (Per week)	Credit	Maximum Marks	Minimum Marks	Exam. Hours	Maximum Marks	Minimum Marks	Exam. Hours
Semester-III										
Major Mandatory Theory	MMI 301	4	--	4	80	32	3	20	8	0.5
	MMI 302	4	--	4	80	32	3	20	8	0.5
	MMI 303	4	--	4	80	32	3	20	8	0.5
Major Elective Theory	E-MMI 304A OR E-MMI 304 B	4	--	4	80	32	3	20	8	0.5
Major Mandatory Practical	P-MMI 305	--	4	2	50	20	6	--	--	--
Research Project	RP-MMI 306	--	8	4	100	40	12#	--	--	--
Total				22	470			80		
Semester-IV										
Major Mandatory Theory	MMI 401	4	--	4	80	32	3	20	8	0.5
Major Elective Theory	E-MMI 402 A OR E-MMI 402 B	4	--	4	80	32	3	20	8	0.5
Research Project	RP-MMI 403	--	28	14	350	140	42##	--	--	--
Total				22	510			40		
Total (Sem III + Sem IV)				44	980			120		

<table>
<tr><td>• MMI – Major Mandatory Theory
• P-MMI – Major Mandatory Practical
• E-MMI – Major Elective Theory
• RP-MMI - Research Project</td><td>• Total Marks for M.Sc.-II: 1100
• Total Credits for M.Sc.-II (Semester III & IV): 44
• Separate passing is mandatory for University and Internal Examinations</td></tr>
<tr><td colspan="2"># Evaluation Scheme for Research Project shall be decided by concerned BOS</td></tr>
<tr><td colspan="2">## Evaluation Scheme for Research Project shall be decided by concerned BOS</td></tr>
<tr><td colspan="2">Requirement for Exit after Level 6.5:
Students can exit after completion of Level 6.5 with Post Graduate in Medical Information Management</td></tr>
</table>

Course Code Details: NEP – Medical Information Management (NEP – 2020)

Semester I		Semester II	
MMI 101	Introduction to Biological Sciences (4 Cr)	MMI 201	Clinical Data and Quality Management (4 Cr)
MMI 102	Medical Informatics (4 Cr)	MMI 202	Clinical Quality Management-I (4 Cr)
E-MMI 103A OR E-MMI 103B	German Language A1 (4 Cr) **OR** Cell Biology, Microbiology and Virology (4 Cr)	E-MMI 203	Clinical Data Management-I (4 Cr)
P-MMI 104	Laboratory Course - I (4 Cr)	P-MMI 204	Laboratory Course - III (4 Cr)
P-MMI 105	Laboratory Course - II (2 Cr)	P-MMI 205	Laboratory Course - IV (2 Cr)
RM-MMI 106	Research Methodology (4 Cr)	OJT-MMI 206 **OR** FP-MMI 206	On Job Training (4 Cr) **OR** Field Project (4 Cr)
Semester III		**Semester IV**	
MMI 301	Clinical Quality Management-II (4 Cr)	MMI 401	Python for Clinical Research (4 Cr)
MMI 302	Project Management and Project Presentation (4 Cr)	E-MMI 402 A OR E-MMI 402 B	NGS for Human Health and Diseases (4 Cr) OR Clinical Biochemistry II (4 Cr)
MMI 303	Module to Deepen Knowledge, Clinical Research, Biostatistics and Epidemiology (4 Cr)	RP-MMI 403	Research Project (14 Cr)
E-MMI 304 A OR E-MMI 304 B	Clinical Data Management –II (4 Cr) OR Clinical Biochemistry I (4 Cr)		
P-MMI 305	Laboratory Course - V (2 Cr)		
RP-MMI 306	Research Project (4 Cr)		

6. Programme Outcomes (POs):

- Students would be able to gain knowledge in fundamental concepts of Biomolecules, pharmacology, endocrinology, computers, workstation, and servers. The student would also get sufficient knowledge of various databases, database formats, drug designing, molecular modeling, medical informatics, etc.
- Student would become well versed with the composition of sequences, protein and gene sequence analysis, protein structure prediction and analysis, molecular docking, molecular dynamics simulations, etc.
- Student would be well acquainted with clinical data management and analysis, clinical quality management and analysis, project presentation, biostatistics, Next Generation Sequencing for human health and disease data analysis, python programming for clinical research, etc.
- Candidate would i) gain capability of handling independent research projects; ii) develop skills for planning and successful execution of the experiment relevant to research problems and iii) be able to analysis of the data obtained and report the results in a meaningful way.

Course Codes:

M.Sc. Semester – III	
Major Mandatory	
MMI 301 Clinical Quality Management-II (4 Cr)	**MSU0325MML930I1**
MMI 302 Project management and Project Presentation (4 Cr)	**MSU0325MML930I2**
MMI 303 Module to Deepen Knowledge, Clinical Research, Biostatistics and Epidemiology (4 Cr)	**MSU0325MML930I3**
P-MMI 305 Laboratory Course - V (2 Cr)	**MSU0325MMP930I1**
RP-MMI 306 Research Project (4 Cr)	**MSU0325RPP930I**
Major Elective	
E-MMI 304A Clinical Data Management –II (4 Cr) OR E-MMI 304B Clinical Biochemistry I	**MSU0325ME930I1**
M.Sc. Semester – IV	
Major Mandatory	
MMI 401 Python for Clinical Research (4 Cr)	**MSU0325MML930J1**
RP-MMI 403 Research Project (14 Cr)	**MSU0325RPP930J**
Major Elective	
E-MMI 402 A NGS for Human Health and Diseases (4 Cr) OR E-MMI 402 B Clinical Biochemistry II	**MSU0325MEL930J1**

6. Syllabus:

SEMESTER III

MMI301	Clinical Quality Management-II (4 Cr)	60 Hrs
CREDIT I	**Before and After Good Laboratory Practices (GLP) and GoodClinical Practices (GCP)** i. Quality system ii. Standard Operating Procedure (SOP) iii. Quality Control (QC) ,Quality Assurance (QA) iv. Quality system evolution v. Clinical protocol audits	**15 Hrs**
CREDIT II	**Training and computing in regulated environment** i. Training of staff ii. QA inspection iii. 21 CFR Part 11 iv. Validation and risk assessment v. Biometrics	**15 Hrs**
CREDIT III	**Quality assurance (QA) activities and beyond compliance** i. Inspections ii. Quality Metrics iii. Audit procedures iv. Other quality systems v. Sampling for quality	**15 Hrs**
CREDIT IV	**Business improvement and Audits** i. Managing quality ii. Responsibilities: QA and Management iii. Qualified person iv. Business continuity plan v. Good Quality System	**15 Hrs**

Reference Books

1. A practical guide to quality management in clinical trial research. Graham D. Ogg. CRC Press,Taylor & Francis Group. USA

MMI302	Project Management and Project Presentation (4 Cr)	60 Hrs
CREDIT I	**Setting Up the Project Management Operation** i. Project management introduction ii. Project Initiation techniques, milestones iii. Implementing a computer-based project management capability iv. Project life cycles, critical Path, critical chain, and uncertainty v. Exploring concepts of shared resource and workforce management	15 Hrs
CREDIT II	**Elements of Resource Management, budgeting and riskmanagement** i. Resource leveling and games of chance ii. Concepts and issues of project budgeting and cost control iii. Software support for cost management iv. Risk management and contingency v. Making project management work	15 Hrs
CREDIT III	**Clinical studies project management** i. Drug development and industry trends ii. Contract research organizations iii. Role of clinical study project manager iv. Goals and standards v. Managing clinical trial activities and processes	15 Hrs
CREDIT IV	**Clinical Project management Resources** i. Budgets, time, resources ii. Measurements, communications iii. Clinical project management training iv. Surviving quality assurance audits v. Troubleshooting in project management	15 Hrs

Reference Books:

1. Practical Project Management Tips, Tactics, and Tools. Harvey A. Levine. John Wiley &Sons, Inc. 2002. Published by John Wiley & Sons, Inc., USA.
2. Clinical research manual practical tools and templates for managing clinical research. R.Jennifer Cavalieri, Mark E. Rupp. 2013. Sigma Theta Tau International. USA.
3. Clinical studies management a practical guide to success. 2004. Simon Cook Interpharm /CRC.

MMI 303	**Module to deepen Knowledge Clinical Research, Biostatistics, Epidemiology (4Cr)**	**60 Hrs**
CREDIT I	**Clinical Trials and outcome measures** i. Clinical trials as research ii. Context for clinical trials iii. Clinical trials as experimental designs iv. Random errors and bias v. Types of outcome measures	**15 Hrs**
CREDIT II	**Clinical Research and CADD** i. Process of CADD in pharmaceutical industry ii. Design and analysis of phase I, II, III trials iii. Randomization iv. Systematic reviews and meta-analysis v. Setting up, conducting and reporting trials vi. Health related quality of life and health economic evaluation	**15 Hrs**
CREDIT III	**Biostatistics** i. Sampling for community health surveys ii. Scales of measurement iii. Constructing a survey questionnaire iv. Validity and reliability of survey questionnaires v. Scales of measurement and methods of data collection	**15 Hrs**
CREDIT IV	**Epidemiology** i. Introduction to Epidemiology ii. Measuring health and disease iii. Types of study iv. Causation and prevention in epidemiology v. Communicable disease epidemiology	**15 Hrs**

Reference Books

1. Clinical trials a methodologic perspective. 2nd edition. 2005. Steven Piantadosi. A JohnWiley & Sons, Inc., Publication. UK
2. A concise guide to clinical trials. Allan Hackshaw. 2009. A John Wiley & Sons, Ltd.,Publication. UK.
3. Biostatistics. A foundation for analysis in the health sciences. Wayne W. Daniel. 9th Edition.2009. John Wiley & Sons, Inc. USA.
4. Handbook of health survey methods edited by Timothy P. Johnson. John Wiley & Sons, Inc.2015. USA.
5. Research methods in community medicine. Surveys, epidemiological research, Programmeevaluation, clinical trials. J. H. Abramson. 2008. John Wiley & Sons Ltd. UK.
6. Basic epidemiology, 2nd ed. Bonita, Ruth, Beaglehole, Robert, Kjellström, Tord & WorldHealth Organization. 2006.

E-MMI 304A	Clinical Data Management II (4 Cr)	60 Hrs
CREDIT I	**Study Startup** i. Data Management Plan ii. Case Report Form (CRF) design consideration iii. Database design considerations iv. Edit checks v. Preparing to receive data	**15 Hrs**
CREDIT II	**Study Conduct** i. Receiving data on paper, overseeing data collection ii. Cleaning data, iii. Managing lab data and Non-CRF data iv. Collecting adverse event data v. Creating reports and transferring data	**15 Hrs**
CREDIT III	**Study Closeout and infrastructure** i. Study database lock ii. After database lock iii. Standard Operating Procedures iv. Training, Control access and security v. Working with Clinical Research Organizations (CROs)	**15 Hrs**
CREDIT IV	**Clinical Data Management Systems** i. EDC systems ii. Choosing vendor products iii. Implementation and validation of new systems iv. Test procedure and change control v. Migrating and Archiving Data	**15 Hrs**

Reference Books

1) Practical guide to Clinical Data Management. 3rd Edition. 2012 by Taylor & Francis Group,LLC, USA.

OR

E- MMI 304 B	**Clinical Biochemistry – I**	**60 Hrs**
Credit I	**Nutrition** Major and minor nutrients, composition of food - calorific values, physiological fuel value, biological value and nitrogen balance. Protein calorie malnutrition, Kwashiorkar and Marasmus. Nutrition in childhood, pregnancy old age and disorders such as diabetes, obesity, coronary disorders and in starvation. **Laboratory Setup And Safety** Requirements of setting up of clinical laboratory, SI units in clinical laboratory, collection preparation, preservation, and handling of clinical samples, quality control, Safety measures in clinical laboratory. Formulation of clinical and diagnostic kits, Safety aspects.	**15 Hrs**
Credit II	**Enzymes and Analytes in Clinical Biochemistry** Use of LDH, SGPT, SGOT, acid and alkaline phosphatase, amylase, lipase, cholesterol, albumin, creatinine etc. in diagnosis and monitoring of disorders **Blood** Total and differential blood count, blood groups and Rh factor incompatibility, plasma proteins, types of anaemias and porphyries, molecular basis of hemoglobinopathies.	**15 Hrs**
Credit III	**Liver** Bilirubin metabolism, types of jaundice and clinical assesment, Acute and chronic liver diseases, cirrhosis, viral, metabolic and drug induced/toxic liver diseases, liver cancer, liver function tests, non-invasive investigations of liver function. **Kidney** Glomerular filtration rate, Renal threshold and clearance values, disorders of kidney, renal failure and proteinuria, renal tubular disorders and renal stones Renal function tests, artificial kidney. **Heart** Ischemic heart disease, role of enzymes and other proteins in assessment of myocardial infarction. Hypertension – types and causes of hypertension, basis of drug therapy for hypertension.	**15 Hrs**
Credit IV	**Carcinogenesis** Tumor cells and onset of Cancer, Characteristics of neoplastic and transformed cells, mechanism of metastasis, Angiogenesis, A multi-hit model of cancer induction, Mutations: Gain and loss of function mutations, Accumulation of mutations and cancer, Oncogenes: RAS, SARC, ABL, Tumor suppresors. **Causes of Cancer** Genetic factors, Viruses, Chemical carcinogenesis, Physical stresses, Hormonal factors **Cancer Therapy** Radiation, Chemotherapy and Immunotherapy	**15 Hrs**

Suggested Readings

1. Clinical Chemistry by Kaplan L.A. and Pesce A. J. C. V. Mosby, 1989

2. Clinical Biochemistry by W. J. Marshall and S. K. Bangert, Churchill Livinston N.Y. 1995
3. Practical Clinical Biochemistry (Varley) by Gowenlock
4. Biochemical Aspects of Human Diseases by Elkeles and Tavill
5. Cancer Biology by Raymond Ruddon
6. Oncogenes by Burck Liu and Larrick
7. Toxicology by Stewart and Stoleman

P-MMI305	Laboratory Course V (2 Cr)	(30 hrs) 100 Marks
	Project study: Data Management in Clinical Research. i) Data Management Plan ii) Clinical Data Management SOPs iii) CRO-Sponsor Responsibility Matrix iv) Implementation Plan v) Validation Plan vi) Analysis of docking complex vii) Analysis of MD trajectory viii) Energy calculation of drug molecules for CADD ix) Pharmacophore designing in CADD x) Molecular modeling for drug designing xi) Quality systems xii) Audit preparation xiii) Being ready for regulatory inspections xiv) Pharmacovigilance Medical Writing xv) Real world issues in Pharmacovigilance	

Reference Books:

1. Practical guide to Clinical Data Management. 3rd Edition. 2012 by Taylor & Francis Group,LLC, USA.
2. An introduction to pharmacovigilance. Patrick Waller. 2010. John Wiley & Sons.
3. Pharmacovigilance. 2nd Edition. Ronald Mann. 2007. John Wiley & Sons Ltd
4. Cobert's Manual of Drug Safety and Pharmacovigilance. 2nd Edition. 2012. Jones & BartlettLearning.
5. Pharmacovigilance Medical Writing. A Good Practice Guide. Justina Orleans-Lindsay. 2012.John Wiley & Sons.
6. AutoDock user manual.
7. SPARTAN user manual by Wavefunction, Inc., USA

RP-MMI306	: Research Project (4 Cr)	100 Marks (60 Hrs)

SEMESTER IV

MMI401	Python for Clinical Research (4 Cr)	60 Hrs
CREDIT I	**Introduction to Python:** i) A quick tour of Python (in Colab and/or IDLE) based on (i) for loops using simple minimal features ii) exposure to Python Turtle Graphics (focus is on quick feel of language and basic algorithmic thinking, rather than syntax). iii) History of Python language, overview of its features and uniqueness. **Data Types, Input/Output and Control Structures:** iv) Basic data types of Python, Python Operators, basic input/output; basic control structures (if, if-else, elif, continue, break and pass), v) for loops, while loops, examples based on selective processing (including summing and counting) of natural number sequences for i in range (N)	**15 Hrs**
CREDIT II	**Python Collections:** i) Concept of data structures and different types (sequential/non- sequential, mutable/immutable, static/dynamic, linear/non-linear, ordered/unordered). ii) Python Data Structures: Lists, strings, tuples, sets and dictionaries. Basic handling of collections using loops, exposure to methods associated with each class ofcollections. i i i) Algorithms for sorting and merging collections (with focus on lists).	**15 Hrs**
CREDIT III	**Python Files & Functions:** i) Files: Opening and Closing Files, Access modes, File position, file handling with OS commands, Pickles and Shelves, Reading from url: ii) Functions: Functions as a named unit of code with inputs and outputs, arguments and parameters, positional, keyword and default arguments, Anonymous lambda functions, iii) Concept of recursion, analyzing problems as base case and recursive cases, examples of printing members of a list, summing, checking palindromes, printing countdown, factorial etc.	**15 Hrs**
CREDIT IV	**Classes and Packages:** i) Concept of Object orientation – need for object orientation in relation to software re-use, classes and objects, inheritance, polymorphism; ii) Python classes: definition, inheriting, constructors,	

	overloading, over-riding, class documentation; Exception handling: iii) Types of errors, error handling, Try-except statement; Modules and Packages: Creating modules and packages, import statement, overview of popular packages: math, stat, random. iv) GUIs in Python: Concept of Event driven programming, introduction to Tkinter; v) Regular Expressions in Python; Introduction to database connectivity; Introduction to CGI programming in Python i) Python programming for clinical research: sequence analysis-reading DNA/protein sequences, sequence length and GC %, ORF finding and clinical study design for treatment studies (phases of interventional clinical trials) and observational studies (clinical case reports)	**15 Hrs**

References:

1. Mark S. (2018), Programming in Python 3: A complete Introduction to the PythonLanguage, 2nd Edition, Pearson Education.
2. Lutz M. (2013), Learning Python, O'Reilly Media.
3. Tim J. S., Wayne B. (2015), Python Programming for Biology Bioinformatics andBeyond, Cambridge University Press.
4. Downey A. (2012), Think Python: How to Think Like a Computer Scientist, O'ReillyMedia.
5. Punch W. F., Enbody R. (2016), The Practice of Computing Using Python, 3rd Edition,Pearson Education.
6. Barry P. (2010), Head First Python, O'Reilly Media.
7. Beazley D. M. (2009), Python Essential Reference, Pearson Education.
8. Dawson M. (2010), Python Programming for the Absolute Beginner, 3rd Edition,Cengage Learning.

E-MMI 402A	NGS for Human Health and Diseases (4 Cr)	60 Hrs
CREDIT I	**History & evolution of NGS and types of NGS:** i) First-generation technologies – Sanger dideoxy sequencing, Maxam-Gilbert sequencing.Technologies used in Human Genome Project, Shotgun sequencing, ii) Next (second)-generation and Third-generation sequencing sequencing, NGS platforms, NGS technologies: DNA-seq, RNA-seq, ChIP-seq, Hi-C, Metagenomics, Single cell sequencing. iii) Different sample preparation methods for different type of NGS *(DNASeq, RNASeq*, ChIPSeq, Metagenomics, Single cell), Adaptors, Index, Barcode. iv) Library preparation methods - Bridge amplification, Emulsion PCR. Sequencing methods –sequencing by synthesis, ion semiconductor, SMRT, nanopore.	**15 Hrs**
CREDIT II	**NGS Data formats, Pre-processing and Data Analysis:** i) Data formats overview – FASTQ, subreads,nanopore data, single cell data. Single-end, Paired-end, Mate-pair. ii) NGS Data sources – NCBI SRA, EBI-ENA, DDBJ-SRA, GEO; Retrieving data from data sources - SRA toolkit; Aspera connect. *Iii)* Sequence quality measures – Phred quality score. Quality check *tool* FASTQC, Pre-processing: Trimmomatic, Fastx-toolkit. *iv*) Introduction to NGS Data Analysis: Assembly principles, output file formats, contigs, scaffolds, assembly quality assessment. v) Mapping Principles, tools – BWA, Bowtie, SAMtools, output file formats – BAM, SAM, mapping alignment assessment – no. of reads mapped, concordantreads; Visualisation tools-IGV.	**15 Hrs**
CREDIT III	**Introduction to genome assembly:** i) Introduction to DNA assembly, K-mer, repeats, contig, scaffold, denovo assembly, reference based assembly, *ii) A*pplications of DNA assembly-whole genome assembly, hybrid assembly, transcriptome assembly, metagenome genome study. i*i*i) Assembly algorithms and assembly assessment: Mapping-based method, OLC- based method, DBG-based method and greedy based-algorithms, Tools – Velvet	**15 Hrs**
CREDIT IV	**Transcriptome assembly and repeat annotations:** i) RNA-seq overview, workflow, Mapping RNA-seq reads, denovo vs ii) Referenced based transcriptome assembly, splice variants, Trinity (de novo), functional annotation. iii) Repeat annotation: Repeats – types & classification-tandem repeats, satellite DNA microsatellite/SSR, Direct repeats, inverted repeats, palindromic repeats, interspersed repeats, transposable	**15 Hrs**

	elements, iv) Genetic and evolutionary significance of repeats, application of repeats, repeat databases – Rpbase, *v)* Methods of repeat Identification-Ab initio & Homology based methods.	

References:

1. Arthur M. Lesk, (2007). Introduction to Genomics. Oxford University Press.
2. Sandy B. Primrose and Richard Twyman (2008). Principles of Genome Analysis andGenomics (Third Edition). Blackwell Publishing.
3. Sara El-Metwally, Osama M. Ouda, Mohamed Helmy (2014). Next Generation Sequencing Technologies and challenges in sequence assembly. Springer-Verlag New York.
4. Ali Masoudi-Nejad, Zahra Narimani, Nazanin Hosseinkhan (2013). Next Generation Sequencing and Sequence Assembly:Methodologies and Algorithms. Springer New York.
5. Adam Voshall (2018). Next-Generation Transcriptome Assembly: Strategies andPerformance Analysis. IntechOpen.
6. Michael Chandler, Martin Gellert (2020). Mobile DNA III. Wiley.

OR

E-MMI 402B	Clinical Biochemistry II (4 Cr)	60 Hrs
Credit I	**Inborn Errors Of Metabolism** Disorders associated with carbohydrate metabolism-glycogen storage diseases, galactosemia Protein metabolism – phenylketonuria, albinism, alkaptonuria Lipid metabolism – Niemann – Pick disease, Tay-Sach's disease, I-cell disease Disorders due to chromosomal aberrations – Down's syndrome, Turner's syndrome, Klinefelter's syndrome molecular basis and symptoms.	**15 Hrs**
Credit II	**Ageing** Physiological and biochemical changes in aeging. Different theories of ageing, importance of superoxide dismutase in ageing, plasticity and regeneration.	**15 Hrs**
Credit III	**Endocrine Disorders** Disorders of pituitary, thyroid, pancreatic and adrenal secretions, biochemical assessment, handling of samples, biological and immunological assays, use of ELISA, RIA and IRMA techniques in assay of hormones.	**15 Hrs**
Credit IV	**Neurological And Psychiatric Disorders** Schizophrenia – types, symptoms, antipsychotic drugs Affective disorders - Unipolar and bipolar disorders, antidepressants Alzeimer's disease, Wernicke-Korsakoff syndrome, dementia, Wilson's disease **Metabolic Disorders** Gout, Atherosclerosis, Multiple sclerosis	**15 Hrs**

RP-MMI 403	Research Project (14 Cr)	350 Marks	Hours 210

9. Scheme of Teaching:

- Each theory paper will have 4 lectures of 60 min. per week.
- The theory paper will have classroom teaching of 60 hours per paper per semester.
- The classroom teaching will be done by Blackboard Chalk, Power Point Presentation, various ICT Tools, Question Answer way, Debate, Seminars, Quiz etc.
- The practical teaching will be done initially by theoretical explanation of experiment, procedural explanation, allowing the student to perform the experiment individually, discussion of results, possible outcome of the result and documentation of observations in notebook and recording all the details in journal which will be examined at the of practical examination.

10. Examination Pattern:

Theory:

- University examination will be of 80 marks for 3 hours as per university time-table and internal examination will be of 20 marks for 30 min by the respective teacher for each theory paper.

Practical:

- University examination will be conducted for practical after theory examination for 4 days including inspection day from 10:30 am to 05:30 pm. There will be no internal examination.

On Job Training:

- The student will submit his/her On Job Training report to the Teacher in Charge after completion of On Job Training. The department will conduct presentation cum viva for all the students. The internal evaluation committee/examiners will assess the On Job Training report and marks will be given.

Field Project:

- The student will submit his/her Field Project report to the Teacher in Charge completion of Field Project. The department will conduct presentation cum viva for all the students. The internal evaluation committee/examiners will assess the Field Project report and marks will be given.

Research Methodology:

- University examination will be of 80 marks and internal examination will be of 20 marks for Research Methodology theory paper.

11. Nature of Question Paper and Scheme of Marking:

a) University Theory Examination:
Skeleton of theory question paper:

M.Sc. Part – II/Sem. – III/IV Examination – 2020 (NEP - 2020)

Medical Information management

Title of the Subject

(Subject Code)

Day & Date: **Total Marks**: 80

Time:

Instructions: 1) Question No. 1 is **COMPULSORY**.

2) All questions carry **EQUAL** marks.

3) Solve any **FOUR** questions such that at least **TWO** questions must be from **EACH** section.

Q. 1 Objective (16 Marks)

16 one line answer type questions

SECTION-I

Q.2 Essay type question (16 Marks)

Q.3 Essay type question (16 Marks)

Q.4 Essay type question (16 Marks)

SECTION-II

Q.5 Write notes on (2 x 08 Marks)

2 sub questions

Q.6 Write short notes on (4 x 04 Marks)

4 sub-questions

Q.7 Write short notes on (4 x 04 Marks)

4 sub-questions

The theory examination will be conducted by the department as per the university examination time-table. The appointment of Chairman, Paper setters, paper assessment, moderation, appointment of internal/external Sr. Supervisor, Junior supervisor, Clerk and Peon for examination and other theory examination work will be carried out as per the university rules and regulations.

b) Internal Theory Examination:

The internal theory examination of 20 marks will be conducted by Teacher in-charge of the respective subject during the semester. The internal examination theory will have 20 questions of 1 mark each. The internal theory paper will be solved on same question paper. Separate answer book will not be given. The examination time will be 30 mins. The internal theory marks will be submitted or uploaded in the university examination portal as per the instructions given by the examination section of the university.

c) University Practical Examination:

The university practical examination will be conducted in the department immediately after the theory examinations. The duration of practical examination will be 4 days including inspection day. The examination for both practical papers will be conducted simultaneously. The day, date, nature of question paper, marks distribution and internal/ external examiners will be decided by theory examination Chairman in consultation with practical paper in charge and laboratory staff. The separate sanction/approval will be required from examination section for practical examination time-table.

12. Equivalence of Courses:

M. Sc. Part II (Semester III and IV)

Old Course				Equivalent Course		
Sem No.	Course Code	Title of the Old Course	Credit	Course Code	Title of the New Course	Credit
Semester III						
III	CC 301	Clinical Data Management II	4	E-MMI 304A	Clinical Data Management –II	4
III	CC 302	Clinical Quality Management-II	4	MMI 301	Clinical Quality Management-II	4
III	DSE 303	Project Management and Project Presentation	4	MMI 302	Project management and Project Presentation	4
III	DSE 304	Module to deepen Knowledge Clinical Research, Biostatistics, Epidemiology	4	MMI 303 A	Module to Deepen Knowledge, Clinical Research, Biostatistics and Epidemiology	4
III	CCPR 305	Laboratory Course	4	-	-	-
III	AEC 306	-	-	-	-	-
III	EC 307	SWMMOOC) Intellectual Property	4	-	-	-
Semester IV						
IV	CCS 401	Phase I: Research Problem Identification and Review of Literature		-	-	-
IV	CCS 402	Phase II: Synopsis submission and Presentation		-	-	-
IV	DSE 403	Phase III: Mid Term Evaluation by Presentation		-	-	-
IV	CCS 404	Phase IV: Hard Bound Submission and Presentation		-	-	-
IV	CCPR 405	Phase V: Viva Voce		-	-	-