SHIVAJI UNIVERSITY, KOLHAPUR

Syllabus for

M.Sc. Part II
Medical Information Management
(CBCS Pattern)

Semester III and IV

From 2020

M.Sc. Medical Information Management CBCS Pattern (2020-21)

M.Sc. Part-II

	Sr. No.	Course code	Teaching Scheme			Examination Scheme					
			Theory and Practical			University Assessment (UA)			Internal Assessment (IA)		
			Lectures (per week)	Hours (per week)	Credit	Maximum Marks	Minimum Marks	Exam. Hours	Maximum Marks	Minimum Marks	Exam. Hours
SEMESTER-III											
CGPA	1	CC-301: Clinical Data Management II	4	4	4	80	32	3	20	8	1
	2	CC-302: Clinical Quality Management-II	4	4	4	80	32	3	20	8	1
	3	DSE-303: Project Management and Project Presentation	4	4	4	80	32	3	20	8	1
	4	DSE-304: Module to deepen Knowledge Clinical Research, Biostatistics, Epidemiology	4	4	4	80	32	3	20	8	1
	5	CCPR-305: Laboratory Course	16	16	8	200*#	80	-	-	-	#
Total (C)			**-**	**-**	**24**	**520**	**-**	**-**	**80**	**-**	**-**
Non-CGPA	1	AEC-306	2	2	2	-	-	-	50	20	2
	2	EC (SWMMOOC)-307: Intellectual Property	5	5	4	-	-	-	-	-	-
SEMESTER-IV											
CGPA	1	CCS 401: Phase I: Research problem identification and review of literature	-	-	4	-	-	-	100	40	-
	2	CCS 402: Phase II: Synopsis submission, and presentation.	-	-	4	-	-	-	100	40	-
	3	CCS 403 : Phase III: Mid-term evaluation by presentation	-	-	4	-	-	-	100	40	-
	4	CCS 404 : Phase IV: Hard-bound submission and presentation	-	-	8	-	-	-	200	80	-
	5	CCPR 405: Phase V: Viva voce	-	-	4	-	-	-	100	40	-
Total (D)			**-**	32	24	-	-	-	600*#	240	-
Non-CGPA	1	SEC-406	2	2	2	-	-	-	50	20	2
	2	GE-407: Research Methodology and Entrepreneurship	2	2	2	-	-	-	50	20	2
Total (C + D)			**-**	**-**	**48**	**520**	**-**	**-**	**680**	**-**	**-**

* Practical examination will be Internal/External as per department choice.

Duration of practical examination will be four days (1 Inspection day & 3 Practical days).

I. CGPA course:

1. There shall be 10 Core Courses (CC) per program.
2. There shall be 02 Discipline Specific Elective (DSE) courses of 08 credits per program.
3. There shall be 04 Core Course Specialization (CCS) courses of 16 credits per program.
4. Total credits for CGPA courses shall be of 96 credits per program.

II. Mandatory Non-CGPA Courses:

1. There shall be 02 Mandatory Non-CGPA compulsory Ability Enhancement Course (AEC) of 02 credits each per program.
2. There shall be 02 Mandatory Non-CGPA Compulsory Skill Enhancement Course (SEC) of 02 credits per program.
3. There shall be one Elective Course (EC) (SWAYAM/MOOC). The credits of this course shall be as specified on SWAYAM/MOOC portal.
4. There shall be one Generic Elective (GE) course of 02 credits per program. Each student has to take Generic Elective from the department other than parent department.
5. The total credits for Non-CGPA course shall be of 08 credits+2to 4 credits, as specified of the SWAYAM/MOOC portal.
6. The credits assigned to the course and program shall have no relation with the work load of the teacher.

12. Scheme of teaching and examination

(Applicable to University Department and University affiliated college centers)

The semester examination will be conducted at the end of each term (theory examination only)
Theory paper will be of 80 marks each and 20 marks for internal evaluation test conducted in the mid of the term. Sem III practical of of 200 marks will be conducted annually. However, M.Sc. Dissertation (Research Project) will be continuously internally evaluated throughout the semester IV.
Question papers will be set in the view of the entire syllabus and preferably covering each unit of the syllabus.

13. Standard of Passing

As per rules and regulations of M.Sc. course.

14. Nature of Question Paper and Scheme of Marking

Nature of question paper and scheme of marking
Theory question paper Maximum marks – 80
Total No. Of question -7
All questions are of equal marks. Out of these seven questions five questions are to be attempted.
Question No.1 is compulsory.
Remaining 6 questions are divided into two sections, namely section-I and Section-II. Four questions are to be attempted for these two sections such that not more than two question from any of the section. Both sections are to be written in the same answer book.
M.Sc. Dissertation of 600 marks will be continuously internally evaluated throughout the semester IV.

Theory question paper format

M. Sc. II Sem III: Medical Information Management (CBCS)

Total marks: 80

Instructions: 1) Question no.1 is compulsory and carries 16 marks

2) Attempt any two questions from each section

3) All questions carry equal marks

Q.1 Objective/multiple choice/one line sentence type 16 questions (16 Marks)

i)

ii)

iii)

iv)

v)

vi)

vii)

viii)

ix

x)

xi)

xii)

xiii)

xiv)

xv)

xvi)

Section-I

Q.2 long answer question (16 Marks)

Q.3 long answer question (16 Marks)

Q.4 long answer question (16 Marks)

Section-II

Q.5 short answer questions (16 Marks)

i)

ii)

Q.6 Short note answer questions (16 Marks)

i)

ii)

iii)

iv)

Q.7 Short note answer questions (16 Marks)

i)

ii)

iii)

iv)

For Sem IV: M.Sc. Dissertation (Research Project) (600 Marks)

M.Sc. Dissertation (Research Project) will be submitted by students and will be continuously internally evaluated by department faculty members. The process of dissertation submission, and evaluation will be as follows;

Course Code	Process of Dissertation (Research Project) submission and evaluation	Credits	Marks distribution
CCS 401	**Phase I:** Research problem identification and review of literature.	04	100 Marks
CCS 402	**Phase II:** Synopsis submission, and presentation.	04	100 Marks
CCS 403	**Phase III:** Mid-term evaluation by presentation	04	100 Marks
CCS 404	**Phase IV:** Hard-bound submission and presentation	08	200 Marks
CCPR 405	**Phase V:** Viva voce	04	100 Marks
	Total	**24**	**600 Marks**

SYLLABUS OF M. Sc. II MEDICAL INFORMATION MANAGEMENT DEGREE COURSES OFFERED by

Department of Biochemistry

Shivaji University, Kolhapur

M.Sc. II Medical Information Management Syllabus

	SEMESTER III	**600 Marks**
CC 301	**: Clinical Data Management II**	
CC 302	**: Clinical Quality Management-II**	
DSE 303	**: Project Management and Project Presentation**	
DSE 304	**: Module to deepen Knowledge** **Clinical Research, Biostatistics, Epidemiology**	
CCPR 305	**: Laboratory Course**	
AEC 306	**: Mandatory Non-CGPA Compulsory Ability Enhancement Course (AEC)**	
EC 307	**: (SWMMOOC) Intellectual Property**	
	SEMESTER IV	**600 Marks**
	: M.Sc. Dissertation (Research Project)	
CCS 401	**Phase I:** Research problem identification and review of literature	
CCS 402	**Phase II:** Synopsis submission, and presentation.	
CCS 403	**Phase III:** Mid-term evaluation by presentation	
CCS 404	**Phase IV:** Hard-bound submission and presentation	
CCPR 405	**Phase V:** Viva voce	
SEC 406	**: Mandatory Non-CGPA Compulsory Skill Enhancement Course**	
GE 407	**: Research Methodology and Entrepreneurship**	

SEMESTER III

	CC 301: Clinical Data Management II	**Total Hours: 60**
Unit 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
Unit 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
Unit 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
Unit 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

Reference Books

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

	CC 302: Clinical Quality Management-II	Total Hours: 60
Unit I	**Before and After Good Laboratory Practices (GLP) and Good Clinical 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
Unit 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
Unit 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
Unit 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

Reference Books

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

	DSE 303: Project Management and Project Presentation	Total Hours: 60
Unit 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
Unit II	**Elements of Resource Management, budgeting and risk management** 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
Unit 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
Unit 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

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.

	DSE 304: Module to deepen Knowledge Clinical Research, Biostatistics, Epidemiology	Total Hours: 60
Unit 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
Unit 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
Unit 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
Unit 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

Reference Books:

1. Clinical trials a methodologic perspective. 2nd edition. 2005. Steven Piantadosi. A John Wiley & 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, Programme evaluation, clinical trials. J. H. Abramson. 2008. John Wiley & Sons Ltd. UK.
6. Basic epidemiology, 2nd ed. Bonita, Ruth, Beaglehole, Robert, Kjellström, Tord & World Health Organization. 2006.

7. An introduction to Computational Biochemistry. (C. Stain Tsai, A John Wiley and Sons, Inc., publications).
8. Bioinformatics Methods and Applications Genomics, Proteomics and Drug Discovery. (Rastogi S. C. Mendiratta, and Rastogi P.)

CCPR 305: Laboratory Course (120 hrs) 200 Marks

Part A:

Project study: Data Management in Clinical Research. (Various projects related to the topics mentioned below will be given to the students.)

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

Part B:

Project study: Quality Management in Clinical Research and Drug Safety (Various projects related to the topics mentioned below will be given to the students.)

i. Quality systems
ii. Audit preparation
iii. Being ready for regulatory inspections
iv. Pharmacovigilance Medical Writing
v. Real world issues in Pharmacovigilance
vi. Pharmacophore designing in CADD
vii. Molecular modeling for drug designing

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 & Bartlett Learning.
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

	AEC 306 : Mandatory Non-CGPA compulsory Ability Enhancement Course	**30 Hrs**
Unit I	Syllabus and nature of paper will be opted as per committee decision.	**15 Hrs**
Unit II		**15 Hrs**

	EC 307 (SWMMOOC): Non-CGPA Elective Course **Intellectual Property**	
Unit I	Syllabus and nature of paper will be opted as per swayam portal.	
Unit II		

SEMESTER IV

Course Code	M.Sc. Dissertation (Research Project) (360 Hrs. Total 600 Marks)
CCS 401	**Phase I:** Research problem identification and review of literature.
CCS 402	**Phase II:** Synopsis submission, and presentation.
CCS 403	**Phase III:** Mid-term evaluation by presentation
CCS 404	**Phase IV:** Hard-bound submission and presentation
CCPR 405	**Phase V:** Viva voce
	Total

	M.Sc. Dissertation (Research Project) from following broad areas for the whole Sem IV)
	• Clinical research • Data management • Quality Management in clinical research • Drug safety • Computer-Aided Drug designing, development and Analysis • Molecular modeling in drug designing **(**Specific topic for each student will be decided based on student's interest in the above mentioned areas and / or supervisor suggestion**)**

	SEC 406 : Skill Enhancement Course	30 Hrs
Unit I	Syllabus and nature of paper will be opted as per committee decision.	**15**
Unit II		**15**

	GE 407 :Generic Elective: Research Methodology and Entrepreneurship	30 Hrs
Unit I	**Research methodology** Aims and objectives of research, Types of research – basic, novel and applied research. Tools for searching research topic – books, journals, internet, discussions etc. Research hypothesis, Steps in research design. Research Aptitude, Qualities of a researcher, Ethics in research – plagiarism **Intellectual Property Rights** Copyright, Trademark, geographical indicators, design, Patent**,** Role of patent in R & D, Criteria for patentability, Indian patent act, Provisional and final patent filing, writing claims, procedure for patent granting	**15 Hrs**
Unit II	**Entrepreneurship Development** Definitions, types, characteristics of Entrepreneur, Basics of Start-Ups, Definition of micro, small and medium scale industries, government facilities and subsidies/financial institutes supporting Start-Ups, Steps in setting up a business, selecting a business idea, market survey, information, market segmentation, market trends, SWOT analysis, **Preparation of a Project Report** Executive summary, Project description, Marketing plan, Capital structure and operating cost, Management/Financial/Technical plan, Project implementation.	**15 Hrs**