Program Framework, Scheme, and Outcomes

Program Name: Masters of Science in Clinical Research

CHAPTER- 1: PROGRAM OBJECTIVES AND OUTCOMES

About the Program:

Program Name: MSc Clinical Research

M. Sc. in Clinical Research is a 04 semester research based postgraduate programme that deals with the human clinical trials. Human clinical trials is the most important areas of medical research which specifically deals with the study of new therapeutic intervention on the group of human volunteers to provide the useful information generate information in the treatment diagnosis prevention of the disease in close alignment with National & International regulations.

This programme will broaden student's exposure for the knowledge regulatory affairs, clinical trial planning & conduct, ethics, writing etc. The programme will also enable students to understand, analyze clinical trial data and to provide the critical in-depth interpretation for the generation of key evidences to improve the patient care. The programme provide sufficient in hand exposure in gaining expertise in research and development processes. The four semester program is design to provide the complete subject specific knowledge to the students, which they can apply best of their knowledge and produce concrete results with learning.

Vision:

To become a globally recognized institute in the field of Biosciences and health care learning where the students are nurtured in a vibrant and conducive environment aimed to create quality workforce who would sustain the ever-increasing challenges of health science and strive for the welfare of the society to become world leaders in the field of clinical research

Mission:

1. Evolve a curriculum which emphasizes in the liberal arts and provides flexibility to choose desired courses for holistic development of the students.
2. Cultivate and disseminate knowledge that provides integrative skills for translational research to bridge the gap between academia and industry.
3. Inculcate leadership qualities in students to have competitive edge with peers and serve the society in better ways

Program Educational Objectives (PEOs)

- **PEO1**: Define, identify, describe & recognize the application of clinical research in a global, economic, environmental and societal context.
- **PEO2**: Describe, classify, explain & demonstrate the regulatory perspectives and processes, standards and practices of ICH-GCP in conduct of ethical clinical trials.
- **PEO3**: Illustrate, relate, and demonstrate the necessary knowledge for developing and managing clinical trials as required and regulated by global regulatory agencies.
- **PEO4**: Demonstrate critical thinking & skills to enhance employment opportunities or advancement within the clinical research industry.
- **PEO5**: Effectively communicate and collaborate with health care service providers and regulatory agencies to develop culturally diverse domestic and global strategies for new product approvals

Mapping of PEO & MO

PEO\MO	MO 1	MO 2	MO 3
PEO 1	**3**	**3**	**2**
PEO 2	**3**	**3**	**2**
PEO 3	**3**	**3**	**2**
PEO 4	**3**	**2**	**3**
PEO 5	**2**	**3**	**3**

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

Program Outcomes: (POs)

After completion of the program, the student will be able to:

Sr No	Outcome	Heading	Description
1	**PO 1**	**Knowledge Enhancement**	Apply knowledge of medical sciences and clinical research in various subject domain of clinical research industry
2	**PO 2**	**Critical Thinking & Problem Analysis**	Design & demonstrate the key skills to perform the clinical trial study from the formulation, implementation to submission
3	**PO 3**	**Modern Tool Usage**	Create, select and apply appropriate technical tools in clinical trial management
4	**PO 4**	**Ethics**	Understand the professional ethical responsibility and demonstrate them in their work place effectively.
5	**PO 5**	**Communication**	Enumerate the International & National regulatory process involved in clinical research & apply them effectively in writing SOPs, licensing & approvals etc.
6	**PO 6**	**Individual & Team work**	Function effectively in team, as individual & as team leader in diverse role
7	**PO 7**	**Life Long Learning**	Recognize the ever changing need of industry and be ready to learn, adapt and engage in skill development

Programme Specific Outcomes: (PSOs)

PSO 1: Demonstrate competency in clinical research organizations (CRO) in trial designs and regulatory affairs management to meet the needs of industry with effective demonstration of advanced critical thinking skills necessary to enhance employment opportunities or advance within the CRO industry

PSO 2: Effectively assess & evaluate critical national and global regulatory issues that challenge and influence new product development

PSO 3: Demonstrate competencies in evaluating clinical research data & effectively communicate and collaborate with health care providers and regulatory agencies to develop culturally diverse national and global strategies for product approvals

CHAPTER 2: PROGRAMME OF STUDY

1. ASU Credit System

The system is designed with the standard international course credit at its core. Each course credit roughly equals three hours of work per week for sixteen weeks (One Semester).

1 Course Credit = 3 hrs of work per week for 16 weeks (approximately)

Work includes lectures, tutorials, practical periods, preparatory work, and assignments.

As per ASU approach of liberal arts, a student can take any subject at any time provided he/she has completed the pre-requisite for that subject.

2. Range of Qualification/Credits essential for Diploma/Degree

Levels	Qualification	Credits
Level 8	**Post-Graduate Diploma (2 semesters):** Post-Graduate Diploma in (Field of study/discipline). Programme duration: One year (two semesters) in the case of those who exit after successful completion of the first year (two semesters) of the 2-year master's programme, followed by an exit 10-credit bridge courses lasting two months, including at least 6-credit job-specific internship/apprenticeship that would help the graduates acquire jobready competencies required to enter the workforce..	30
Level 9	**Master's degree (4 semesters)**: Programme duration: Two years (four semesters) for those who have obtained a 3-year/6-semester bachelor's degree, or one year (two semesters) in the case of those who have obtained a 4-year/8-semester Bachelor's (Honours/Research) degree.	60
Level 9	**Master's degree (2 semesters)**: Programme duration: One years (two semesters) for those who have obtained a 3-year/6-semester bachelor's degree, or one year (two semesters) in the case of those who have obtained a 4-year/8-semester Bachelor's (Honours/Research) degree.	30

3. Minimum qualifications

To earn M. Sc. Degree in Clinical Research, student must earn a minimum of 60 credits.

S, No	Degree Requirement	Credits
1	Knowledge/skill domain courses	06
2	Open Elective & Community Service	01
3	Major	53
	Total Credits	60

4. Structure of Program Curriculum :

Core courses (Major)	Discipline-specific electives	Knowledge/Skill domain courses(LA)	Interdisciplinary electives	Community Service	Industrial Project/ Research Project	Internships (Summer Industrial training)/ Dissertation	Total Credits
31	08	06	-	01	02	12	60

5. Semester wise credit distribution

Instead of signing up for the average of 15 credits per semester, a student can sign up for a minimum of 12 credits with a maximum of 18 credits. It includes knowledge/skill domain courses, open electives and major degree courses (freedom to choose any course offered every semester by the university). The basic graduation requirement is 60 units.

Course Code distribution major degree courses:

1) Fundamental (Course Code) …… 501-510; 601-610
2) Depth (Course Code) …… 511 -530; 611-630
3) Degree Elective (Course Code)……. 651--660
4) Summer Industrial Training/Industrial Project (Course Code)/ Research Project/ Dissertation ……. 650;700

Pre-requisites: A course or other requirement that a student must have taken prior to enrolling in a specific course

Table for Credit distribution

Sr No	Category of course	Course Code	Course Title	Pre req Code	Pre requisites	Credit	Lecture Hours/ week	Tutorial hours/ week	Practical hours/ week	Others
1	Fundamentals	BSBT501	Biostatistics	Nil		3	3	1	3	2
2	Fundamentals	BSCR601	Clinical Research: Fundamentals & Principals	Nil		3	3	1	2	3
3	Fundamentals	BSCR602	Fundamentals of Epidemiology	Nil		3	3	1	3	3

4	Fundamentals	BSCR603	Fundamentals of Public Health	Nil		3	3	1	3	3
5	Fundamentals	BSCR604	Clinical Pharmacology	Nil		3	3	1	3	2
6	Fundamentals	BSCR605	New Drug Discovery & Development	Nil		3	3	1	3	2
7	Fundamentals	BSBT505	Research Methodology	Nil		3	3	1	2	3
8	Depth	BSCR611	Bioethics	BSCR601	Clinical Research: Fundamentals & Principals	3	3	1	2	3
9	Depth	BSCR612	Clinical Trials	Nil		3	3	1	2	3
10	Depth	BSCR613	Medical Writing	BSCR601	Clinical Research: Fundamentals & Principals	3	3	1	2	3
11	Depth	BSCRRegulatory	Regulatory Affairs	BSCR601	Clinical Research: Fundamentals & Principals	3	3	1	2	3
12	Depth	BSCR615	Quality Control and Assurance in Clinical Trials: GCP	BSCR614	Regulatory Affairs	3	3	1	2	3

13	Depth	BSCR616	Disease Biology and Therapeutics	BSCR604	Clinical Pharmacology	3	3	1	2	3
14	Depth	BSCR617	Pharmacovigilance	BSCR611	Bioethics	3	3	1	2	3
15	Depth	BSCR618	Clinical Data management	BSBT501	Biostatistics	3	3	1	2	3
16	Depth	BSCR619	Clinical case Study	BSCR601; BSCR612;	Clinical Research: Fundamentals & Principals; Clinical Trials	3	3	1	2	3
17	Depth	BSCR620	Health Economics: Clinical Research	Nil		3	3	1	2	3
18	Depth	BSCR621	Clinical Trial Management	BSCR612	Clinical Trials	3	3	1	2	3
19	Depth	BSCR 622	AI in Healthcare			3	3	1	2	3
20	Depth	BSCR 623	Mathematical Modelling of Disease Transmission	BSBT501	Biostatistics		3	1	2	3
21	Depth	BSBT517	IPR	Nil		3	3	1	2	3
22	Depth	BSBT521	Molecular & Immunodiagnostics	Nil		3	3	1	2	3
23	Depth	BSBT525	Scientific Writing and Critique	BSBT505	Research Methodology	3	3	1	2	3
24	Degree Electives	BSCR651	Epidemiology	BSCR601; BSCR60	Clinical Research:	4	2	1	2	7

				2; BSCR603; BSBT501	Fundamentals & Principals; Fundamentals of Epidemiology; Fundamentals of Public Health; Biostatistics					
25	Degree Electives	BSCR652	Clinical Trial Project Management	BSCR612; BSCR620	Clinical Trials ; Fundamentals of Epidemiology;	4	2	1	2	7
26	Degree Electives	BSCR653	Business Development	BSCR601; BSCR612; BSCR620	Clinical Research : Fundamentals & Principals ; Clinical Trials; Fundamentals of Epidemiology	4	2	1	2	7

27	Degree Electives	BSCR654	Clinical Trial Data Analyst	BSBT501; BSCR612; BSCR618	Biostatistics; Clinical trials; Clinical Data management	4	2	1	2	7
28	Degree Electives	BSCR655	Policy Development	BSCR601; BSCR612; BSCR602; BSCR603; BSCR620	Clinical Research: Fundamentals & Principals; Fundamentals of Public Health Clinical Trials; Fundamentals of Epidemiology;	4	2	1	2	7
29	Degree Electives	BSCR656	Medical Coding & Database Design	BSBT501; BSCR612; BSCR621; BSCR618	Biostatistics; Clinical trials; Clinical Trial management;	4	2	1	2	7

					Clinical Data Management					
30	Degree Electives	BSCR657	IPR& Regulatory Affairs	BSCR601; BSCR611; BSCR612; BSCR614; BSCR613; BSBT517;	Clinical Research: Fundamentals & Principals; Bioethics; Regulatory Affairs; Medical Writing; IPR	4	2	1	2	7
31	Degree Electives	BSCR658	Clinical Auditor	BSCR601; BSCR612; BSCR613; BSCR614; BSCR615; BSCR621;	Clinical Research: Fundamentals & Principals; Clinical Trials; Medical Writing; Regulatory Affairs;	4	2	1	2	7

					Quality Control and Assurance in Clinical Trials: GCP; Clinical Trials					
32	Degree Electives	BSCR 659	Bioinformatics	BSBT501; BSBT521; BSCR617; BSCR618	Biostatistics; Molecular & Immunodiagnostics; Pharmacovigilance; Clinical Data management	4	2	1	2	7
30	Research/ Dissertation	BSCR650	Research Project			2	1	1	1	3
31	Research/ Dissertation	BSCR700	Dissertation			12	2	3	1	30

Semester Flow Diagram:

Semester	Courses	Credits
Semester 1	(i) Knowledge/skill domain course/Open electives (ii) Major degree requirement	06 credits 09 credits
Semester 2	(i) Major degree requirement	16 credits
Semester 3	(i) Major degree requirement (ii) Degree Electives (iii) Research	06 credits 04 credits 02 credits
Semester 4	(i) Community service (ii) Degree Electives (iii) Dissertation	01 credits 04 credits 12 credits
	Total Credits	60

CHAPTER-3: COURSE STRUCTURE AND OUTCOMES

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 601	Major (Fundamental)	Clinical Research: Fundamentals & Principals	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction to Clinical Research Definition, History: Galen experiments, James Lind experiments, Concept of randomization, Tuberculosis, Streptomycin study, Tuskegee Experiments, Nazi Experiment, Nuremberg code, Helsinki Declaration, Thalidomide study**,** Belmont Report, Current scenario of Clinical research in India, New career opportunities in clinical	REMEMBER History: Galen experiments, James Lind experiments, Concept of randomization, Tuberculosis, Streptomycin study, Tuskegee Experiments, Nazi Experiment, REMEMBER, DESCRIBE Nuremberg code, Helsinki Declaration, Thalidomide study**,** Belmont Report, EXPLAIN AND DISCUSS Current scenario of Clinical research in India, New career opportunities in clinical	**BSCR601_CO1 :** Describe the historical development & recognize the social impact in Clinical Research	**1**

research, Different area of Clinical research: Clinical trials, Clinical Data management, Bioequivalence & bioavailability, Quality assurance, Medical writing, Pharmacovigilance & their responsibilities	research, Different area of Clinical research: Clinical trials, Clinical Data management, Bioequivalence & bioavailability, Quality assurance, Medical writing, Pharmacovigilance & their responsibilities		
Unit II: Drug Development Process (Clinical Research) High throughput screening (HTS), Lead optimization, target-centered drug design, Problems in extrapolating data from animals to humans, Concept of *in silico* drug designing, Concept of Pharmacogenomics	UNDERSTAND: High throughput screening (HTS), Lead optimization, target-centered drug design, DEFINE, DESCRIBE Problems in extrapolating data from animals to humans, Concept of *in silico* drug designing, Concept of Pharmacogenomics	**BSCR601_CO2:** Demonstrate & explain the drug development process in clinical research	**2**
Unit III: Formulation Development Introduction to different formulations, advantages and disadvantages of common formulations, Introduction to manufacturing of drugs and Good Manufacturing Practices (GMP), Quality assurance and quality control during manufacturing a drug,	APPLY: Introduction to different formulations, advantages and disadvantages of common formulations, Introduction to manufacturing of drugs and Good DEMONSTRATE, DISCUSS Manufacturing Practices (GMP), Quality assurance and quality control during manufacturing a drug,	**BSCR601_CO3:** Explain & demonstrate the process of quality assurance in drug development process	**3**

Biopharmaceutical classification on drugs	DEFINE, DEMONSTRATE Biopharmaceutical classification on drugs		
Unit IV: Regulatory **authority** ICH-GCP, Indian GCP, Schedule Y, Protocol designing & development emphasis to IB; Ethical committee IEC and its composition, Clinical Study report, Key player's of clinical trial, International Scenario of Regulatory Aspects : FDA, CFR; Regulatory aspects of medical devices, biological & Electronic Submissions, Dossier filing. Basic concepts of Intellectual Property rights	APPLY AND DISCUSS: ICH-GCP, Indian GCP, Schedule Y, Protocol designing & development emphasis to IB; DEFINE, REMEMBER, APPLY AND DISCUSS Ethical committee IEC and its composition, DEFINE, DESCRIBE, APPLY AND DISCUSS Clinical Study report, Key player's of clinical trial, International Scenario of Regulatory Aspects : FDA, CFR; DEFINE, DISCUSS Regulatory aspects of medical devices, biological & Electronic Submissions, Dossier filing. Basic concepts of Intellectual Property rights	**BSCR601_CO4:** Express the role of regulators and drug development process	**3**
Unit V: Drug Evaluation and Clinical Development Phases of developmental clinical trials, Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV, Placebo response, advantages and disadvantages of placebo	ANALYZE: Phases of developmental clinical trials, Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV, Placebo response, advantages and disadvantages of placebo	**BSCR601_CO5:** Scientifically differentiate the phase of clinical trial	**5**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR601_CO 1	3			3	2			1	2	-
BSCR601_CO 2	2	3	2			2	2	2	-	-
BSCR601_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR601_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR601_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR601_CO1	20
2	BSCR601_CO2	20
3	BSCR601_CO3	20
4	BSCR601_CO4	20
5	BSCR601_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR601_CO1	1,2,3,4,7	1,4,5
2	BSCR601_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR601_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR601_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR601_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

9. Bibliography and References

Prescribed Texts:

- Principles and Practice of Clinical Research- John I. Gallin, Frederick P. Ognibene2007
- Designing Clinical Research- Stephen B. Hulley, Steven R. Cummings, Warren S. Browner · 2011
- Essentials of Clinical Research- Stephen P. Glasser · 2014

Reference Books:

- Drug Safety: From Molecule To Man- Park
- Drugs: From Discovery To Approval - NG
- Manual Of Clinical Microbiology- Murray
- Patient Care In Community Practice- Harman
- Introduction To Clinical Pharmacology- Edmunds

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 602	Major (Fundamental)	Fundamentals of Epidemiology	3	1	3	2	3	Nil

Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I Introduction to Epidemiology Introduction & Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation of Epidemics and New	REMEMBER Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, UNDERSTAND Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation of Epidemics and New Diseases, Biologic Spectrum of Disease, Surveillance of Community Health	BSCR602_CO1 Describe the epidemiology, philosophy and applications	1

Diseases, Biologic Spectrum of Disease, Surveillance of Community Health Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease.	Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease		
Unit II Epidemiologic Data Analysis Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates Standardization of Death Rates, Rates for Maternal and Infant Health	ANALYZE, EVALUATE Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates, Standardization of Death Rates, Rates for Maternal and Infant Health	BSCR602_CO2 Analyze, Interpret & explain the epidemiology relationship with statistics	3
Unit III Epidemiologic Surveillance and Epidemic Outbreak Investigation Surveillance of Disease: Role of Surveillance, Creation of Surveillance System, Methods	ANALYZE Surveillance of Disease: Role of Surveillance, Creation of Surveillance System, Methods and Functions of Disease Surveillance, Establishment of	BSCR602_CO3 Hypothesize & Design the Disease Surveillance Model to identification of epidemic outbreak	4

and Functions of Disease Surveillance, Establishment of Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures	Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures		
Unit IV Research Designs and Issues in Epidemiology Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological Studies, Observational Designs, Cohort Studies, Case-Control Studies, Nested Case-Control Studies, Randomized Controlled Clinical Trials, Randomized	DEMONSTRATE, APPLY, PREPARE, ANALYZE COMPARE, DEVELOP Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological Studies, Observational Designs, Cohort Studies, Case-Control Studies, Nested Case-Control Studies, Randomized	BSCR602_CO4 Design the Epidemiology Study	3

Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues	Controlled Clinical Trials, Randomized Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues		
Unit V Assessment of Risk and Benefit in Epidemiologic Studies Definition Of Study Groups, Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit Analysis, Application of Risk Measures to Counselling of Patients	**RECOGNIZE, CLASSIFY, CALCULATE, PRIORITIZE, ASSESS** Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit Analysis, Application of Risk Measures to Counselling of Patients	BSCR602_CO5 Assessment & Evaluation of risk in Epidemiological Studies	4

Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR602_CO 1	3	-	-	3	2	-	-	2	2	-
BSCR602_CO 2	3	3	2	1	2	2	3	2	3	3
BSCR602_CO 3	2	3	3	2	2	3	-	2	3	3
BSCR602_CO 4	3	3	2	2	3	2	2	2	3	3
BSCR602_CO 5	2	3	3	2	2	3	2	2	3	3

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR602_CO1	20
2	BSCR602_CO2	20
3	BSCR602_CO3	20
4	BSCR602_CO4	20
5	BSCR602_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR602_CO1	1,2,3,4,7	1,4,5
2	BSCR602_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR602_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR602_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR602_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

9. Bibliography and References

Text books

- High-Yield Biostatisitcs, Epidemiology and Public Health- AN Glaser
- Modern Epidemiology- Rothman, Greenland & Lash

- Biostatistics and Epidemiology: A Primer for Health and Biomedical Professionals- Smoller & Smoller
- Introduction to Epidemiology: Merrill

Internet

- WHO: Epidemiolgy http://www.who.int/topics/epidemiology/en/
- The BMJ http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/1-what-epidemiology
- CDC Epidemiology http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section1.html

Reference Material (Journals, Hand-outs)

Journals-

- Epidemiology- http://journals.lww.com/epidem/Pages/default.aspx
- Journal of Epidemiology & Community Health http://jech.bmj.com/

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 603	Major (Fundamental)	Fundamentals of Public Health	3	1	3	2	3	Nil

Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I Introduction to Public Health Definition and determinants of Public Health: Evolution of the science of public health Prevention Determinants of Health: Nutrients, Lifestyle, Socioeconomic, Genetic	DESCRIBE, REMEMBER, RELATE Definition and determinants of Public Health: Evolution of the science of public health Prevention Determinants of Health: Nutrients, Lifestyle, Socioeconomic, Genetic	BSCR603_CO1 Describe the Public Heath, philosophy and applications	1
Unit II Epidemiologic in Indian Context Epidemiological Transition, Global Health, Functional organization of the public health system in India and	UNDERSTAND, DISCUSS Epidemiological Transition, Global Health, Functional organization of the public health system in India and categorical health services,	BSCR603_CO2 Identify & relate the epidemiological transitions and public health program run by global and Indian agencies	2

categorical health services, overview of National health and family welfare programmes, Primary Health Care, Millennium Development Goals, India :Health indicators, urban-rural profile, National Rural Health Mission	Overview of National health and family welfare programmes, Primary Health Care, Millennium Development Goals, RELATE, DESCRIBE India :Health indicators, urban-rural profile, National Rural Health Mission		
Unit III National Health Policies Community perceptions on health and disease, Sources of health data: Birth and Death Registries, Disease Registries, Population based data, eg. NFHS data, Sources of Global Health Data, Introduction to National Health Policy –1983 & 2002, National Population Policy –2005, National Rural Health Mission (NRHM) and National Urban Health Mission (NUHM), National Public Health Programs.	ANALYZE, RELATE, DISUCSS, INTERPRET Community perceptions on health and disease, Sources of health data: Birth and Death Registries, Disease Registries, Population based data, eg. NFHS data, Sources of Global Health Data, Introduction to National Health Policy –1983 & 2002, National Population Policy –2005, National Rural Health Mission (NRHM) and National Urban Health Mission (NUHM), National Public Health Programs.	BSCR603_CO3 Understand , relate, discuss & describe the Registry systems, population policies of Indian Govt	3
Unit IV Health Indicators Comparison of health	DEFINE, DEMONSTRATE, APPLY, PREPARE,	BSCR603_CO4 Relate & apply the knowledge in	4

indicators of selected developed and developing countries, Functional organization of the public health system: Primary Health Centres (PHCs)-Sub–Centres (SCs), Data Collection to provide an insight into community demographics, socio–economic status, types and distribution of diseases and disorders in the community	COMPARE, DEVELOP, DISTINGUISH Comparison of health indicators of selected developed and developing countries, Functional organization of the public health system: Primary Health Centres (PHCs)-Sub–Centres (SCs), Data Collection to provide an insight into community demographics, socio–economic status, types and distribution of diseases and disorders in the community	identification of health indicators	
Unit V Demographics Methods of demographic data collection-Sources of data, Population Census, Population composition, World population growth, Growth of Indian population, Fertility, Mortality, Migration/urbanization, Population projections, Life tables, Population policy	ANALYZE, CLASSIFY, EVALUATE, PRIORITIZE, ASSESS PLAN, COMPARE Methods of demographic data collection-Sources of data, Population Census, Population composition, World population growth, Growth of Indian population, Fertility, Mortality, Migration/urbanization, Population projections, Life tables, Population policy	BSCR603_CO5 Prioritize, Classify & Plan the methods for the demographic studies	4

Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR603_CO 1	3	1	-	3	2	-	-	2	2	-
BSCR603_CO 2	3	2	2	1	2	2	2	2	3	2
BSCR603_CO 3	2	3	3	2	2	3	2	2	3	3
BSCR603_CO 4	2	3	3	1	2	2	2	2	2	3
BSCR603_CO 5	2	3	2	2	2	3	2	2	3	3

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR603_CO1	20

2	BSCR603_CO2	20
3	BSCR603_CO3	20
4	BSCR603_CO4	20
5	BSCR603_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR603_CO1	1,2,3,4,7	1,4,5
2	BSCR603_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR603_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR603_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR603_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

10. Bibliography and References

Text books

- Oxford text book of Public Health Ed. Roger Detels, James Mcewen, Robert Beagle hole, and Heizo Tanaka Oxford University Press
- Public Health at the Crossroads–Achievements and Prospects. Robert Beagle hole and Ruth Bonita Cambridge University Press
- Preventive and Social Medicine, K Park, Bansaridas Bhanot Publishing House

Internet

- WHO: public health http://www.who.int/topics/public_health/en/
- http://www.icmr.nic.in
- http://www/nfhs.nic.in

Reference Material (Journals, Hand-outs)

Journals-

- Public Health
- Journal of public health

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 604	Major (Fundamental)	Clinical Pharmacology	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: General pharmacology Introduction to pharmacology, Definition, scope of pharmacology, sources of drugs, route of drug administration, competitive and non-competitive inhibition, Pharmacokinetics, Process, kinetics of inhibition, elimination, excretion	DEFINE, REPEAT, REMEMBER, DESCRIBE Introduction to pharmacology, Definition, scope of pharmacology, sources of drugs, route of drug administration, competitive and non-competitive inhibition, Pharmacokinetics, Process, kinetics of inhibition, elimination, excretion	**BSCR604_CO1 :** Describe role of Pharmacology with its applications	**1**
Unit II: Pharmacodynamics Principles and mechanism of action, Drug receptors, G-protein coupled receptors, ion	DEFINE, DESCRIBE, EXPLAIN, EXPERIMENT AND DISCUSS: Principles and mechanism of action, Drug receptors, G-	**BSCR604_CO2:** Demonstrate & explain the Pharmacodynamics of drug	**2**

channel receptors, transmembrane enzyme linked receptors, Therapeutic index, Adverse drug reaction, Pharmacovigilance	protein coupled receptors, ion channel receptors, transmembrane enzyme linked receptors, Therapeutic index, Adverse drug reaction, Pharmacovigilance	action	
Unit III: Clinical Trial Drug discovery, clinical evaluation of new drugs, Clinical trial phases in details, Recent clinical trial passed drugs	DEFINE, DEMONSTRATE, DISCUSS Drug discovery process in preclinical and post clinical trials	**BSCR604_CO3:** Explain & demonstrate the process of clinical research	**3**
Unit IV: 4 Pharmacology of drugs Herbal Drugs and Experimental establishment of the drugs (Animal Model and Cell Line), Drugs acting on peripheral nervous system, Drugs acting on Central nervous system, Neuromuscular agents, Antiepileptics, Sedatives and Hypnotics, Antipsychotics, Antidepressants, Antianxiety, Drugs used in Parkinson's Disease, Alzheimer's disease, Drug Database	DEFINE, DESCRIBE, APPLY AND DISCUSS: Herbal Drugs and Experimental establishment of the drugs (Animal Model and Cell Line), DEMONSTRATE Drugs acting on peripheral nervous system, Drugs acting on Central nervous system, Neuromuscular agents, Antiepileptics, Sedatives and Hypnotics, Antipsychotics, Antidepressants, Antianxiety, Drugs used in Parkinson's Disease, Alzheimer's disease, Drug Database	**BSCR604_CO4:** Experiment & Demonstrate the Pharmacology of Herbal Drugs	**4**
Unit V: Pharmacogenomics Introduction, Drug lists based on pharmacogenomics, Socio-	DEFINE, REMEMBER, DESCRIBE AND DISCUSS:	**BSCR604_CO5:** Explain the role and application of Pharmacogenomics in drug	**2**

economic impact, Databases of Pharmacogenomics, Drugs availability, Pharmacogenomics in Cardiovascular system, Diabetes, Cancer, Case studies on Pharmacogenomics	Introduction, Drug lists based on pharmacogenomics, Socio-economic impact, Databases of Pharmacogenomics, Drugs availability, DEMONSTRATE Pharmacogenomics in Cardiovascular system, Diabetes, Cancer, Case studies on Pharmacogenomics	development process	

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR604_CO 1	3	1	2	2	2			1	2	-
BSCR604_CO 2	2	3	3		1	2	3	2	2	2
BSCR604_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR604_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR604_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR604_CO1	20
2	BSCR604_CO2	20
3	BSCR604_CO3	20
4	BSCR604_CO4	20
5	BSCR604_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR604_CO1	1,2,3,4,7	1,4,5
2	BSCR604_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7

3	BSCR604_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR604_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR604_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

9. Bibliography and References

Prescribed Texts:

- Basic and Clinical Pharmacology by Bertram G. Katzung
- The pharmacological basis of Therapeutics by Laurence L. Brunton (Godman and Gilman's)
- Modern Pharmacology with clinical applications by Charles R. Craig and Robert E. Stitzel
- Desk reference of Clinical Pharmacology by Manuchair Ebadi

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 605	Major (Fundamental)	New Drug Discovery & Development	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
UNIT-I: Introduction to Drug Discovery & Development process Target identification, Hit identification, Hit to lead, Lead optimization, Basic understanding of important assays in drug discovery process, Cell free assays, Cell based assays, Ex-vivo target based activity, Physicochemical properties, Solubility, Metabolic stability, In vivo activity (primary model for proof of	DEFINE, REMEMBER, DESCRIBE, DEMONSTRATE Target identification, Hit identification, Hit to lead, Lead optimization, Basic understanding of important assays in drug discovery process, Cell free assays, Cell based assays, Ex-vivo target based activity, EXPERIMENT, DEMONSTRATE Physicochemical properties, Solubility, Metabolic stability, In vivo activity (primary model for proof of concept), In vitro toxicity study (Cytotoxicity in	**BSCR605_CO1 :** Describe & Experiments the process of drug discovery & development	**1**

concept), In vitro toxicity study (Cytotoxicity in various cell Lines, hERG assay to measure cardiotoxicity, In vivo activity (primary disease model), In vivo activity (Disease model), 4 day tox in rat, 14 Days Tox in rat, Other project specific assays, Preclinical development: Basic understanding of GLP/GMP process, Clinical development: Significance of Phase-1,2,3,4 studies	various cell Lines, hERG assay to measure cardiotoxicity, In vivo activity (primary disease model), In vivo activity (Disease model), 4 day tox in rat, 14 Days Tox in rat, Other project specific assays, DEFINE, REMEMBER, DISCUSS Preclinical development: Basic understanding of GLP/GMP process, Clinical development: Significance of Phase-1,2,3,4 studies		
Unit II: Lead optimization: Drug parameters required for lead optimization Physicochemical properties (Log-P, Log-D), Role of Solubility, Kinetic and equilibrium solubility. Methods to improve solubility (Salt formation, Prodrug concept etc), Lipinski Rule, Ghose rule, Vaber's rule, Drug Metabolism: Primary and secondary drug metabolism, Role of drug metabolism in	DEFINE, DESCRIBE, EXPLAIN, EXPERIMENT AND DISCUSS Physicochemical properties (Log-P, Log-D), Role of Solubility, Kinetic and equilibrium solubility. Methods to improve solubility (Salt formation, Prodrug concept etc), Lipinski Rule, Ghose rule, Vaber's rule, Drug Metabolism: Primary and secondary drug metabolism, Role of drug metabolism in drug design, Importance of Cytochrome P450 enzymes in drug discovery, prodrug concept, Soft drug concept	**BSCR605_CO2:** Describe & explain the process of lead optimization	**2**

drug design, Importance of Cytochrome P450 enzymes in drug discovery, prodrug concept, Soft drug concept			
Unit III: Toxicity and other development related issues Drug Transporters: Introduction, Types of transporters, Role of transporters, Regulation of transporters on genetic level, ABC Superfamily, P glycoprotein, SLC transporters, Resistance Toxicophores, Drug -Drug interactions**:** Importance of Cyp induction/inhibition., Cardiotoxicity assays, cytotoxicity assays	DEFINE, EXPERIMENT, DISCUSS Drug Transporters: Introduction, Types of transporters, Role of transporters, Regulation of transporters on genetic level, ABC Superfamily, P glycoprotein, SLC transporters, Resistance Toxicophores, Drug -Drug interactions**:** Importance of Cyp induction/inhibition., Cardiotoxicity assays, cytotoxicity assays	**BSCR605_CO3:** Explain & Experiment the toxicity issues in the drug development process	**4**
UNIT IV Structure-and ligand based drug design: Structure-based drug design: Identification and analysis of Binding sites and virtual screening. molecular docking, Free energies and solvation, electrostatic and non-electrostatic contribution to free energies. Fragment	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Structure-based drug design: Identification and analysis of Binding sites and virtual screening. molecular docking, Free energies and solvation, electrostatic and non-electrostatic contribution to free energies. Fragment based drug design, Zinc data base, Structure-	**BSCR605_CO4:** Experiment & Demonstrate the Structure & Ligand based drug design	**4**

based drug design, Zinc data base, Structure-Activity relationship: QSARs and QSPRs, Methodology, 3D Pharmacophore mapping, De novo Ligand design	Activity relationship: QSARs and QSPRs, Methodology, 3D Pharmacophore mapping, De novo Ligand design		
Unit V: Pharmacogenomics Pharmacogenetics, definition & scope, History Potential impact of pharmacogenomics in healthcare practice. Pharmacogenetics of drug metabolism with examples of clinically important polymorphic enzymes; pharmacogenetics of selected disorders, interethnic differences in drug response; Pharmacogenomics of alcoholism, hypertension, Diabetes, cancer, autoimmune diseases Socio economic impact: clinical implementation	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Pharmacogenetics, definition & scope, History Potential impact of pharmacogenomics in healthcare practice. Pharmacogenetics of drug metabolism with examples of clinically important polymorphic enzymes; pharmacogenetics of selected disorders, interethnic differences in drug response; DEMONSTRATE Pharmacogenomics of alcoholism, hypertension, Diabetes, cancer, autoimmune diseases Socio economic impact: clinical implementation	**BSCR605_CO5:** Explain the role and application of Pharmacogenomics in drug development process	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR605_CO 1	3	1	2	2	2			1	2	-
BSCR605_CO 2	2	3	3		1	2	3	2	2	2
BSCR605_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR605_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR605_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study

Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**

1	BSCR605_CO1	20
2	BSCR605_CO2	20
3	BSCR605_CO3	20
4	BSCR605_CO4	20
5	BSCR605_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR605_CO1	1,2,3,4,7	1,4,5
2	BSCR605_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR605_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR605_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR605_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Drug Discovery and Design; Chemistry, Academic Press, 2001; Vol. Volume 56
- Enzymes as Targets for Drug Design 1989, Academic Press, 1989

- The Organic Chemistry of Drug Design and Drug Action," San Diego: Academic Press, 1992
- Pharmacogenomics methods and protocols, Federico innocenti, Humana press, 2005

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 611	Major (Depth)	Bioethics	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: An introduction to patent law Introduction to patent law,	DEFINE, REMEMBER, DESCRIBE IP, Patent, WTO, Legal	**BSCR611_CO1 :** Define & explain the IP rights in Clinical Research	**1**

World trade organization and intellectual property provisions, Legal protection in research and development. Medical Research related patenting and ethical consideration.	protection in research and development. Medical Research related patenting and ethical consideration.		
Unit II: Introduction to Bioethics: Bioethics Introduction, Importance of Bioethics, Definition of the term Ethics in Biology, Health Ethics and Professional Ethics, History of Bioethics. Ethical principles and its type**.**	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Bioethics Introduction, Importance of Bioethics, Definition of the term Ethics in Biology, Health Ethics and Professional Ethics, History of Bioethics. Ethical principles and its type	**BSCR611_CO2:** Describe & explain the importance of ethics in Clinical Research	**2**
Unit III: Ethical Theories: Forms of ethical theories: Deontology, Utilitarian rights and Virtue. Types of ethical thoughts: Kantian, Rawls and Ross ethics. Duty of fidelity, Duty of justice and Duty of preparation. Duty of gratitude and Duty of beneficence	DEFINE, DISCUSS Ethical theories: Deontology, Utilitarian rights and Virtue. Types of ethical thoughts: Kantian, Rawls and Ross ethics. Duty of fidelity, Duty of justice and Duty of preparation. Duty of gratitude and Duty of beneficence	**BSCR611_CO3:** Explain & Discuss the ethical theories applicable in clinical research	**2**
Unit IV: Healthcare Profession Healthcare profession: Healthcare provider, the client and healthcare provider-client relationship. Basic healthcare	DEFINE, DESCRIBE, APPLY AND DISCUSS Healthcare profession: Healthcare provider, the client and healthcare provider-client relationship. Basic healthcare	**BSCR611_CO4:** Understand the role of healthcare professional in maintaining the client relationship	**3**

principles: Stewardship and totality.	principles: Stewardship and totality.		
Unit V: Biosafety Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)	DEFINE, REMEMBER, DESCRIBE, DISCUSS, APPLY: Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)	**BSCR611_CO5:** Explain the role and application of Bioethics & GMP in Clinical Research	**3**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR611_CO 1	3	1	2	3	2	-	-	1	2	-
BSCR611_CO 2	2	3	3	3	1	-	-	2	2	2
BSCR611_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR611_CO 4	2	2	-	3	1	-	2	2	2	2

BSCR611_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
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3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes

8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR611_CO1	20
2	BSCR611_CO2	20
3	BSCR611_CO3	20
4	BSCR611_CO4	20
5	BSCR611_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	**Course Outcomes**	**Assessment Tools**	**Teaching Tools**

1	BSCR611_CO1	1,2,3,4,7	1,4,5
2	BSCR611_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR611_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR611_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR611_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Bioethics: An introduction for the Biosciences by Ben Mepham (Oxford).
- IPR, Biosafety and Bioethics by Deepa Goel and Shomni Parashar (Pearson pub.)

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 612	Major (Depth)	Clinical Trial	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level

Unit 1: Fundamental of Trial Design Randomized Clinical Trials: Phases, Design, Number of centers, Bias, Systematic errors, Confounding, Random error, Example: CHARM program, Sample Size calculation, End point, Uncontrolled Trials: Rational, Phase trial, Limitations, Investigator bias, Protocol Development: Writing, Guidelines, Implications, Key components of trial design, Trail summary, Flow chart, Eligibility criteria, End point, Enrollment process, Procedure, follow ups, Outcome measure, Statistical issue, Ethics, Regulatory requirements, Monitoring, Publication policy, Study timetable, References, Case record form, Trial committees, Data safety and monitoring board, Endpoints: Types of end point, End point selection, Composite end point, Advantages & Limitations of composite end point, Surrogate end point,	DEFINE, REMEMBER, DESCRIBE, DEMONSTRATE Randomized Clinical Trials: Phases, Design, Number of centers, Bias, Systematic errors, Confounding, Random error, Example: CHARM program, Sample Size calculation, End point, Uncontrolled Trials: Rational, Phase trial, Limitations, Investigator bias, Protocol Development: Writing, Guidelines, Implications, Key components of trial design, Trail summary, Flow chart, Eligibility criteria, End point, Enrollment process, Procedure, follow ups, Outcome measure, Statistical issue, Ethics, Regulatory requirements, Monitoring, Publication policy, Study timetable, References, Case record form, Trial committees, Data safety and monitoring board, Endpoints: Types of end point, End point selection, Composite end point, Advantages & Limitations of	**BSCR612_CO1 :** Define & explain the clinical trial designs	**1**

Advantages & Limitations of surrogate end point, Health economic end point, Advantages & Limitations of Health economic end point; Patient Selection: Source of patient, Investigators & Centers, Eligibility criteria, Disease status, Ethical issue, Source and Control of Bias: Bias in Clinical Research, Selection, Bias in study management, Blinding, Achieving blinding, Publication bias, Randomization: Utility, Minimizing bias, Methods: Simple, Block, Stratified, Adaptive, Blinding: Blinding or Masking, Need, Types: Open/Un blinded, Single blinded, Double blinded, Triple blinded, Coding of drug, Assessment, Sample Size and Power: Effective sample size, factors effecting sample size, Determination & Evaluations, Choosing the power in trial phase, Taking of study dropout in study.	composite end point, Surrogate end point, Advantages & Limitations of surrogate end point, Health economic end point, Advantages & Limitations of Health economic end point; Patient Selection: Source of patient, Investigators & Centers, Eligibility criteria, Disease status, Ethical issue, Source and Control of Bias: Bias in Clinical Research, Selection, Bias in study management, Blinding, Achieving blinding, Publication bias, Randomization: Utility, Minimizing bias, Methods: Simple, Block, Stratified, Adaptive, Blinding: Blinding or Masking, Need, Types: Open/Un blinded, Single blinded, Double blinded, Triple blinded, Coding of drug, Assessment, Sample Size and Power: Effective sample size, factors effecting sample size, Determination & Evaluations, Choosing the power in trial phase, Taking of study dropout in study.		
Unit 2: **Alternative Trial**	DEFINE, DESCRIBE,	**BSCR612_CO2:** Describe &	**2**

Designs Crossover Trials: Classification, Example, Advantages, Limitations, Factorial Design: Utility, Consideration, randomization of factorial design, Sample size, Analysis, Advantages, Limitations, Equivalence Trials: Reason for Equivalence trial, Types: Clinical equivalence, Bioequivalence, Design issues, Noninferiority, Result interpretation, Bioequivalence Trials: PK parameters, Calculations of PK, Bioequivalence of two drug, Noninferiority Trials: Examples, Design, Uses, Advantages, Limitations, Analysis Cluster Randomized Trials: Design of CRT, Selection bias in CRT, Impact of sample size, Statistical methods & Model, Publication bias, Ethical Issues, Advantages & Limitations, Multicenter Trials: Utility, Organization, Meeting requirements, Ethical	EXPLAIN AND DISCUSS Crossover Trials: Classification, Example, Advantages, Limitations, Factorial Design: Utility, Consideration, randomization of factorial design, Sample size, Analysis, Advantages, Limitations, Equivalence Trials: Reason for Equivalence trial, Types: Clinical equivalence, Bioequivalence, Design issues, Noninferiority, Result interpretation, Bioequivalence Trials: PK parameters, Calculations of PK, Bioequivalence of two drug, Noninferiority Trials: Examples, Design, Uses, Advantages, Limitations, Analysis Cluster Randomized Trials: Design of CRT, Selection bias in CRT, Impact of sample size, Statistical methods & Model, Publication bias, Ethical Issues, Advantages & Limitations, Multicenter Trials: Utility, Organization, Meeting requirements, Ethical issues, Center selection, Patient randomization,	Design the Clinical Trial Studies	

issues, Center selection, Patient randomization, Publication policy	Publication policy		
Unit 3: **Basics of Statistical Analysis** Types of Data and Normal Distribution: Data types & Variables, Survival data, Data presentation & Tabulation, Normal distribution: properties, importance, examples, standard normal distribution, Area Under the curve, Significance Tests and Confidence Intervals: Hypothesis testing, Confidence interval, Relationship between significance test and CIs, Comparison of Means: One sample t-test, paired t-test, two sample t-test, Z-test, Wilcoxon rank sum test, multiple group comparison, Comparison of Proportions: Statistical interference for one treatment group, comparing proportion between two groups, Chi-square test, Fishers exact test,	DEFINE, APPLY Types of Data and Normal Distribution: Data types & Variables, Survival data, Data presentation & Tabulation, Normal distribution: properties, importance, examples, standard normal distribution, Area Under the curve, Significance Tests and Confidence Intervals: Hypothesis testing, Confidence interval, Relationship between significance test and CIs, Comparison of Means: One sample t-test, paired t-test, two sample t-test, Z-test, Wilcoxon rank sum test, multiple group comparison, Comparison of Proportions: Statistical interference for one treatment group, comparing proportion between two groups, Chi-square test, Fishers exact test, Assessment of size of	**BSCR612_CO3:** Explain & apply the statistical methods in Clinical Trials	**3**

Assessment of size of treatment in two arm trial, Odds ratio, Risk ratio, Analysis of Survival Data: Consoring, Survival function and hazard function, Survival curve, Kaplan-Meier method, Log rank test, Proportional hazard model, Regression model., Risk difference,	treatment in two arm trial, Odds ratio, Risk ratio, Analysis of Survival Data: Consoring, Survival function and hazard function, Survival curve, Kaplan-Meier method, Log rank test, Proportional hazard model, Regression model., Risk difference		
Unit 4: Special Trial Issues in Data Analysis Intention-to-Treat Analysis: Overview, Justification of ITT, Examples, comparison of ITT & PP analysis, Subgroup Analysis: Appropriate size, analysis, patient imbalance, threshold adjustment, interaction test, Post hoc analysis, Regression Analysis; Classification: Multiple linear, logistic, hazard, Common regression model in Clinical trial, Adjustment for Covariates: baseline covariates, rational for adjustment, imbalance, Confounding: Causes, variables characters, positive and negative confounders, methods to control confounders: stratification,	DEFINE, DESCRIBE AND DISCUSS Intention-to-Treat Analysis: Overview, Justification of ITT, Examples, comparison of ITT & PP analysis, Subgroup Analysis: Appropriate size, analysis, patient imbalance, threshold adjustment, interaction test, Post hoc analysis, Regression Analysis; Classification: Multiple linear, logistic, hazard, Common regression model in Clinical trial, Adjustment for Covariates: baseline covariates, rational for adjustment, imbalance, Confounding: Causes, variables characters, positive and negative confounders, methods to control confounders: stratification,	**BSCR612_CO4:** Understand the issues in trial data analysis	**2**

regression model, Interaction: Interaction effects, Classification, Evaluation, Examples, treatment by period interaction, Repeated Measurements: Key considerations, strategies for repeated measure data, time by time analysis, use of statistical models, use of summary measure, Multiplicity: Multiple end point, Multiple treatment, repeated measurements, interim analysis, strategies to deal with multiplicity: change of p-value, relative meaning of multiple outcome, Missing Data: common types of missing data, Potential effects, strategies to deal with missing data, Interim Monitoring and Stopping Rules : Uses, types, procedure, statistical methods, situations	regression model, Interaction: Interaction effects, Classification, Evaluation, Examples, treatment by period interaction, Repeated Measurements: Key considerations, strategi es for repeated measure data, time by time analysis, use of statistical models, use of summary measure, Multiplicity: Multiple end point, Multiple treatment, repeated measurements, interim analysis, strategies to deal with multiplicity: change of p-value, relative meaning of multiple outcome, Missing Data: common types of missing data, Potential effects, strategies to deal with missing data, Interim Monitoring and Stopping Rules : Uses, types, procedure, statistical methods, situations.		
Unit 5: : **Reporting of Trials** Overview of Reporting: Structure and quality of reports, internal validity, external validity, sufficient information, CONSORT statement, problems in	DEFINE, REMEMBER, DESCRIBE, APPLY AND DISCUSS: Overview of Reporting: Structure and quality of reports, internal validity,	**BSCR612_CO5:** Explain & Describe the clinical trial reporting	**3**

reporting, Trial Profile; Inclusion, purpose, design: two way parallel, 2x2 factorial design, two way crossover design, Presenting Baseline Data: Inclusion, significance test, imbalance factors, Use of Tables: Standard tables, Complex tables, Use of Figures: characteristics, types: Bar, Histo, Box, Forest, Scatter, Critical Appraisal of a Report, Meta-Analysis	external validity, sufficient information, CONSORT statement, problems in reporting, Trial Profile; Inclusion, purpose, design: two way parallel, 2x2 factorial design, two way crossover design, Presenting Baseline Data: Inclusion, significance test, imbalance factors, Use of Tables: Standard tables, Complex tables, Use of Figures: characteristics, types: Bar, Histo, Box, Forest, Scatter, Critical Appraisal of a Report, Meta-Analysis		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR612_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR612_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR612_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR612_CO	2	2	-	3	1	1	2	2	2	2

4										
BSCR612_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports

6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR612_CO1	20
2	BSCR612_CO2	20
3	BSCR612_CO3	20
4	BSCR612_CO4	20
5	BSCR612_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR612_CO1	1,2,3,4,7	1,4,5
2	BSCR612_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR612_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR612_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR612_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Clinical Trial: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines
- A Comprehensive and Practical Guide to Clinical Trials-Brenda Wright, Delva Shamley
- Fundamentals of Clinical Trials-Lawrence M. Friedman
- Textbook of Clinical Trials-David Machin, Simon Day, Sylvan Green
- Biostatistics In Clinical Trials- Redmond
- Drug Safety Assessment In Clinical Trials- Gilbert

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics

- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 613	Major (Depth)	Medical Writing	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction Article writing: types, good publication practices, Searching the scientific literature, Using the Online library, Using online search engines, What is a refereed journal? Plagiarism and how to	DEFINE, REMEMBER, DESCRIBE, Article writing: types, good publication practices, Searching the scientific literature, Using the Online library, Using online search engines, What is a refereed	**BSCR613_CO1 :** Define & explain the scientific writing process	**1**

avoid it, Beginning to Write: Establishing your constraints, Organizing your writing, Preparing outlines, Standard formats for scientific papers, research projects and theses Style guides	journal? Plagiarism and how to avoid it, Beginning to Write: Establishing your constraints, Organizing your writing, Preparing outlines, Standard formats for scientific papers, research projects and theses Style guides		
Unit II: Writing & Review Creating a literature review, Preparing other sections of a research report (abstract, introduction, materials and methods, results and discussion, conclusions), Including and summarizing research data, Style and grammar , Scientific writing style, First-person vs. Third-person; Passive vs. active voice, Avoiding excessive wording, Grammar, Avoiding misuse of words, When to use footnotes, Reference citations, How to use references, Within the text, How to make lists of references	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Creating a literature review, Preparing other sections of a research report (abstract, introduction, materials and methods, results and discussion, conclusions), Including and summarizing research data, Style and grammar , Scientific writing style, First-person vs. Third-person; Passive vs. active voice, Avoiding excessive wording, Grammar, Avoiding misuse of words, When to use footnotes, Reference citations, How to use references, Within the text, How to make lists of references	**BSCR613_CO2:** Describe & Design the scientific review article	**2**
Unit III: Revising & Presentation Dealing with revisions, Accepting criticism, Making	DEFINE, EXPERIMENT, DISCUSS Dealing with revisions, Accepting criticism, Making	**BSCR613_CO3:** Explain & apply the tools for scientific presentation & review the	**2**

sense of reviewers' comments, Making the changes, What to do if you don't agree with reviewers' comments Other communication: Other types of scientific writing, research proposals, creating a fact sheet/bulletin, articles for popular press, memos, letters and emails, Poster organization and formats for posters, Using Microsoft PowerPoint, Oral Presentations, Designing and preparing slides for an oral presentation, Importing tables, charts and graphs from Excel, Optimizing pictures for use in presentations, Using visual aids without overdoing it, Using Microsoft PowerPoint	sense of reviewers' comments, Making the changes, What to do if you don't agree with reviewers' comments Other communication: Other types of scientific writing, research proposals, creating a fact sheet/bulletin, articles for popular press, memos, letters and emails, Poster organization and formats for posters, Using Microsoft PowerPoint, Oral Presentations, Designing and preparing slides for an oral presentation, Importing tables, charts and graphs from Excel, Optimizing pictures for use in presentations, Using visual aids without overdoing it, Using Microsoft PowerPoint	reports and papers	
Unit IV: Guidelines for medical writing Duties of Author, Authorship dispute, Editor, Reviewer, etc., Guidelines of ICMJE and other bodies, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities, Publication Ethics, Journal quality and impact assessment	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Duties of Author, Authorship dispute, Editor, Reviewer, etc., Guidelines of ICMJE and other bodies, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities, Publication Ethics, Journal	**BSCR613_CO4:** Understand the guidelines for the medical writing	**3**

of article, Common technical document (CTD) dossier writing	quality and impact assessment of article, Common technical document (CTD) dossier writing		
Unit V: Documents in Clinical Research Clinical study report, Grant proposal, Leave behind literature, Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc.	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Clinical study report, Grant proposal, Leave behind literature, Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc.	**BSCR613_CO5:** Explain & Describe the essential documents for the clinical research process	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR613_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR613_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR613_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR613_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR613_CO	1	-	-	3	-	-	1	2	-	2

5										

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR613_CO1	20
2	BSCR613_CO2	20
3	BSCR613_CO3	20
4	BSCR613_CO4	20
5	BSCR613_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR613_CO1	1,2,3,4,7	1,4,5

2	BSCR613_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR613_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR613_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR613_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Macrina FL. Teaching authorship and publication practices in the biomedical and life sciences. Sci Eng Ethics. 2011 Jun;17(2):341-54. Epub 2011 May 1. PubMed PMID: 21533836.
- Carpenter CR, Cone DC, Sarli CC. Using publication metrics to highlight academic productivity and research impact. Acad Emerg Med. 2014 Oct;21(10):1160-72. doi: 10.1111/acem.12482. PubMed PMID: 25308141.
- Provenzale JM. Revising a manuscript: ten principles to guide success for publication. AJR Am J Roentgenol. 2010 Dec;195(6):W382-7. PubMed PMID: 21098168

Internet:

1. http://grants.nih.gov/grants/writing_application.htmCDSCO, www.cdsco.nic.in
2. http://ori.hhs.gov/sites/default/files/plagiarism.pdf
3. http://www.nature.com/nature/journal/v481/n7379/full/481021a.html
4. http://www.sciencemag.org/content/335/6075/1439.1.long

Reference Material (Journals, Handout)

1. Nature
2. PNAS
3. PlosOne
4. Any scientific journals

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 614	Major (Depth)	Regulatory Affairs	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
UNIT I Evolution of Regulatory controls: An international comparison, Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki, ICH, NICE	DEFINE, REMEMBER, DESCRIBE, Evolution of Regulatory controls: An international comparison, Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki, ICH, NICE	**BSCR614_CO1 :** Define & explain the regulatory controls in clinical research	**1**
UNIT II Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Paper NDA, Market authorization holders (MAH), its procedures, Post-marketing	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Paper NDA, Market authorization holders (MAH),	**BSCR614_CO2:** Describe the process of drug regulatory process for new discovery	**2**

Surveillance (PMS),	its procedures, Post-marketing Surveillance (PMS),		
UNIT III US FDA regulations, Regulation of medical devices, Regulation of vaccines, Safety Report filing, Regulation of prescription drugs and non prescription drugs, Regulatory system in Key countries: Japan, Australia, China and Brazil	DEFINE, EXPERIMENT, DISCUSS US FDA regulations, Regulation of medical devices, Regulation of vaccines, Safety Report filing, Regulation of prescription drugs and non prescription drugs, Regulatory system in Key countries: Japan, Australia, China and Brazil	**BSCR614_CO3:** Explain & define the US FDA regulations in clinical research	**2**
UNIT IV International Conference on Harmonization (ICH) GCP guidelines, Overviews of GLP, Basic regulation of BA/BE studies, Introduction to IPR, patent, copyright, industrial design, Introduction to EMEA, OECD, ANVISA, TGA, Regulation of Traditional and Herbal Remedies	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS International Conference on Harmonization (ICH) GCP guidelines, Overviews of GLP, Basic regulation of BA/BE studies, Introduction to IPR, patent, copyright, industrial design, Introduction to EMEA, OECD, ANVISA, TGA, Regulation of Traditional and Herbal Remedies	**BSCR614_CO4:** Understand the international regulatory guidelines	**3**
Unit V Introduction to New Drug &	DEFINE, REMEMBER, DESCRIBE AND DISCUSS:	**BSCR614_CO5:** Explain & Describe the Indian govt	**2**

Clinical Trial Rules, 2019, Rule 97, regulatory periods, fee, committees, Role of DGCI, CDSCO, Post trial regulation	**Unit V** Introduction to New Drug & Clinical Trial Rules, 2019, Rule 97, regulatory periods, fee, committees, Role of DGCI, CDSCO, Post trial regulation	regulations for the clinical research	

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR614_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR614_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR614_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR614_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR614_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low

2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle

5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR614_CO1	20
2	BSCR614_CO2	20
3	BSCR614_CO3	20
4	BSCR614_CO4	20
5	BSCR614_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR614_CO1	1,2,3,4,7	1,4,5
2	BSCR614_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR614_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR614_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR614_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by US-FDA. 2nd Edition, published by Informa Healthcare. ISBN 1420073540
2. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, by Gary Walsh, John J. Tobin published by Wiley-VCH Verlag GmbH. ISBN 9783527318773
3. Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
4. Principles and Practice of Clinical researxch by John I, Gallin;Academic Press Inc;3rd Edition
5. Regulatory guidelines ICH, USFDA, Indian GCP, EMEA etc

ONLINE RESOURCE MATERIAL AND JOURNALS:

1. Journal of Intellectual Properties Rights
2. The WIPO Journal
3. European Patent Bulletin
4. www.wipo.int
5. www.ficciipcourse.in

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 615	Major (Depth)	Quality Control and Assurance in Clinical Trials: GCP	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction to Operational Quality An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ) Procedures, Validation master plan	DEFINE, REMEMBER, DESCRIBE, EXPERIMENT; DEMONSTRATE An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ) Procedures, Validation master plan	**BSCR615_CO1 :** Define & explain the operational quality controls in clinical research	**1**
Unit II: Prospective Pathway to Drug Discovery Principles of Drug discovery and development. Clinical research process. Development	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Principles of Drug discovery and development. Clinical research process. Development	**BSCR615_CO2:** Describe the process of drug discovery applications and approvals	**2**

and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA)	and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA)		
Unit III: Quality Assurance in Post Approval of Drugs Supplemental New Drug Application (SNDA), Scale Up Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC). Post marketing surveillance, Current Biopharmaceutical regulations and in particular related to Cell Therapy and regenerative medicine.	DEFINE, EXPERIMENT, DISCUSS Supplemental New Drug Application (SNDA), Scale Up Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC). Post marketing surveillance, Current Biopharmaceutical regulations and in particular related to Cell Therapy and regenerative medicine.	**BSCR615_CO3:** Explain & define the quality assurance process in after the approval of drug	**2**
UNIT IV: Pharmaceutical Quality Assurance Components of pharmacopoeia monographs and reference standards, GCP, TQM, Validation, quality audit: quality of equipment, validation of equipment, validation of analytical procedures**.**	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Components of pharmacopoeia monographs and reference standards, GCP, TQM, Validation, quality audit: quality of equipment, validation of equipment, validation of analytical	**BSCR615_CO4:** Understand the quality assurance in pharmaceutical products	**3**

	procedures.		
Unit V: Emerging concepts of Quality Assurance Emerging concepts in quality assurance of drugs: Introduction, Hazard analysis and critical control points (HACCP) methodology. Pharmaceutical Quality Systems (PQS), Quality Review and Quality Documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data.	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Emerging concepts in quality assurance of drugs: Introduction, Hazard analysis and critical control points (HACCP) methodology. Pharmaceutical Quality Systems (PQS), Quality Review and Quality Documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data.	**BSCR615_CO5:** Explain & Describe the Emerging concepts in quality assurance	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR615_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR615_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR615_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR615_CO	2	2	-	3	1	1	2	2	2	2

4										
BSCR615_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports

6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR615_CO1	20
2	BSCR615_CO2	20
3	BSCR615_CO3	20
4	BSCR615_CO4	20
5	BSCR615_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR615_CO1	1,2,3,4,7	1,4,5
2	BSCR615_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR615_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR615_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR615_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

- Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making- Janet Woodcock, Jonathan R. Davis, Vivian P. Nolan, Ronald W. Estabrook
- Total Quality Management Key Concepts and Case Studies – DR Kiran
- Quality Control in Laboratory - Gaffar Zaman
- Textbook of Clinical Trials-David Machin, Simon Day, Sylvan Green
- Drug Safety Assessment In Clinical Trials- Gilbert

Internet:

- American Chemical Society, www.acs.org
- Chemical Abstracts Service, www.cas.org
- International Union for Pure and Applied Chemistry (IUPAC), iupac.org
- International Union of Pharmacology (IUPHAR) Database www.iuphar-db.org
- Drug Bank, www.drugbank.ca
- PubChem, www.pubchem.ncbi.nlm.nih.gov

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 616	Major (Depth)	Disease Biology and Therapeutics	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
UNIT I Homeostasis and Genesis of diseases Concept of homeostasis and normal health, positive and negative feedback mechanisms, receptor control and effector, endocrine regulation in normal health, enzymes in homeostasis. Definition of disease, disorder, stages, scope, causes and transmissibility of diseases, stages of diseases, and epidemiology	DEFINE, REMEMBER, DESCRIBE, Concept of homeostasis and normal health, positive and negative feedback mechanisms, receptor control and effector, endocrine regulation in normal health, enzymes in homeostasis. Definition of disease, disorder, stages, scope, causes and transmissibility of diseases, stages of diseases, and epidemiology	**BSCR616_CO1 :** Define & explain the process of homeostasis and disease genesis	**2**
UNIT II Nutritional,	DEFINE, DESCRIBE,	**BSCR616_CO2:** Describe	**2**

Environmental, and Microbial cause of disease Nutritional disorders, reasons for nutritional diseases, vitamin and micronutrient deficiency disorders, environmental pollutants causing diseases, drug induced diseases, microbial cause of disease, routes and transmission of infection, major microbes causing diseases, eating disorders	EXPLAIN AND DISCUSS Nutritional disorders, reasons for nutritional diseases, vitamin and micronutrient deficiency disorders, environmental pollutants causing diseases, drug induced diseases, microbial cause of disease, routes and transmission of infection, major microbes causing diseases, eating disorders	the disease causing factors	
UNIT III Genetic and Metabolic causes of disease Genetic cause of disease, Monogenic, polygenic cause of disease, Autosomal disorders, Genetotrophic diseases, inborn errors of metabolism, Garrod's hypothesis, types of metabolic disease, Nucleic acid deficiency disease, protein deficiency disorders	DEFINE, EXPERIMENT, DISCUSS Genetic cause of disease, Monogenic, polygenic cause of disease, Autosomal disorders, Genetotrophic diseases, inborn errors of metabolism, Garrod's hypothesis, types of metabolic disease, Nucleic acid deficiency disease, protein deficiency disorders.	**BSCR616_CO3:** Explain & define the genetic and metabolic causes of disease	**2**
UNIT IV Clinical Therapeutics Rational basis of therapeutics (P-drug concept, Essential	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Rational basis of therapeutics (P-drug concept, Essential	**BSCR616_CO4:** Understand the clinical therapeutics process	**3**

drugs) Rational drugs Human and Population Pharmacokinetics, Pharmacodynamics, routes of drug administration, Clinical drug evaluation, Clinical trial designing, Clinical trial ethics, Pharmacovigilance, Drugs and Cosmetics Act ,Data archiving and management Drug audit (Pharmacoepidemiology, Pharmacoeconomics), Therapeutics drug monitoring & individualization of drug therapy	drugs) Rational drugs Human and Population Pharmacokinetics, Pharmacodynamics, routes of drug administration, Clinical drug evaluation, Clinical trial designing, Clinical trial ethics, Pharmacovigilance, Drugs and Cosmetics Act ,Data archiving and management Drug audit (Pharmacoepidemiology, Pharmacoeconomics), Therapeutics drug monitoring & individualization of drug therapy		
UNIT V Pathophysiology and drug therapy Treatment for Environmental, Microbial, Genetic and Metabolic diseases, Drug therapy in Geriatrics, Pediatrics, Pregnancy & Lactation, Renal & hepatic insufficiency	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Treatment for Environmental, Microbial, Genetic and Metabolic diseases, Drug therapy in Geriatrics, Pediatrics, Pregnancy & Lactation, Renal & hepatic insufficiency	**BSCR616_CO5:** Explain & Describe the pathophysiology and drug therapy	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR616_CO	3	1	2	3	2	-	2	1	2	-

1										
BSCR616_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR616_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR616_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR616_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR616_CO1	20
2	BSCR616_CO2	20
3	BSCR616_CO3	20

4	BSCR616_CO4	20
5	BSCR616_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR616_CO1	1,2,3,4,7	1,4,5
2	BSCR616_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR616_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR616_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR616_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Sharma, H. M.; Bodeker, Gerard C (1997). "Alternative Medicine (medical system)". Encyclopedia Britannica (2008 edition).
- Biochemistry by Voet and Voet (2011), published by John Wiley & Sons
- Genes and Disease by Bethesda MD (1998), published by NCBI,US
- Genetics and Evolution of Infectious Disease. Published by Elsevier
- Peptides: Chemistry and Biology by Norbert Sewald, Hans-Dieter Jakubke Softcover,2nd Edition (2009) Wiley-VCH

Reference Material (Journals, Handout)

- Journal of Parasitology
- International Journal for Parasitology
- American Journal of Physiology
- Asian Pacific Journal of Tropical Disease
- Clinical Therapeutic
- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 617	Major (Depth)	Pharmacovigilance	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I INTRODUCTION Introduction to Pharmacovigilance (PV), History & Development of PV, Importance of safety monitoring of Medicine, WHO international drug monitoring programme , Pharmacovigilance Program of India(PvPI), Definition and classification of ADRs,	DEFINE, REMEMBER, DESCRIBE, Introduction to Pharmacovigilance (PV), History & Development of PV, Importance of safety monitoring of Medicine, WHO international drug monitoring programme , Pharmacovigilance Program of India(PvPI), Definition and	**BSCR617_CO1 :** Define & explain the Pharmacovigilance importance and process	**2**

Detection, reporting and causality assessment, Severity and seriousness assessment, Predictability and preventability assessment Management of adverse drug reactions, Pharmacovigilance in India and global perspective, Pharmacovigilance methods, passive surveillance-spontaneous reports and case series, Active surveillance-drug event monitoring and registries, Basic tools used in pharmacovigilance, Safety studies, Importance of pharmacovigilance, Terminologies of adverse medication related events, Regulatory terminologies	classification of ADRs, Detection, reporting and causality assessment, Severity and seriousness assessment, Predictability and preventability assessment Management of adverse drug reactions, Pharmacovigilance in India and global perspective, Pharmacovigilance methods, passive surveillance-spontaneous reports and case series, Active surveillance-drug event monitoring and registries, Basic tools used in pharmacovigilance, Safety studies, Importance of pharmacovigilance, Terminologies of adverse medication related events, Regulatory terminologies		
Unit II Drug and disease classification Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Non proprietary Names for drugs Drug dictionaries and coding	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Non proprietary Names for drugs Drug dictionaries and coding	**BSCR617_CO2:** Describe the classification of drug & disease	**2**

in pharmacovigilance: WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary, Information resources in pharmacovigilance: Basic drug information resources, Specialised resources for ADRs, Establishing pharmacovigilance programme: Establishing in a hospital, Establishment & operation of drugsafety department in industry, Contract Research Organisations (CROs), Establishing a national programme	in pharmacovigilance: WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary, Information resources in pharmacovigilance: Basic drug information resources, Specialised resources for ADRs, Establishing pharmacovigilance programme: Establishing in a hospital, Establishment & operation of drugsafety department in industry, Contract Research Organisations (CROs), Establishing a national programme		
Unit III VACCINE SAFETY SURVEILLANCE Vaccine safety surveillance: Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization, Pharmacovigilance methods: Passive surveillance –	DEFINE, DISCUSS Vaccine safety surveillance: Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization, Pharmacovigilance methods: Passive surveillance –	**BSCR617_CO3:** Explain & define the vaccine safety surveillance system	**2**

Spontaneous reports and case series, Stimulated reporting, Active surveillance – Sentinel sites, drug event monitoring and registries, Comparative observational studies – Cross sectional study, case control study and cohort study, Targeted clinical investigations, Communication in pharmacovigilance: Effective communication in Pharmacovigilance, Communication in Drug Safety Crisis management, Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	Spontaneous reports and case series, Stimulated reporting, Active surveillance – Sentinel sites, drug event monitoring and registries, Comparative observational studies – Cross sectional study, case control study and cohort study, Targeted clinical investigations, Communication in pharmacovigilance: Effective communication in Pharmacovigilance, Communication in Drug Safety		
UNIT IV STATISITCAL METHODS FOR SAFTEY DATA EVALUATION Statistical methods for evaluating medication safety data, Safety data generation, Pre clinical phase, Clinical phase, Post approval phase, ICH Guidelines for Pharmacovigilance, Organization and objectives of	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Statistical methods for evaluating medication safety data, Safety data generation, Pre clinical phase, Clinical phase, Post approval phase, ICH Guidelines for Pharmacovigilance, Organization and objectives of	**BSCR617_CO4:** Understand the process of safety data evaluation	**3**

ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies	ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies		
UNIT V Pharmacogenomics of ADR Pharmacogenomics of adverse drug reactions, Drug safety evaluation in special population, Paediatrics, Pregnancy and lactation, Geriatrics, CIOMS, CIOMS Working Groups, CIOMS Form, CDSCO (India) and Pharmacovigilance, D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Pharmacogenomics of adverse drug reactions, Drug safety evaluation in special population, Paediatrics, Pregnancy and lactation, Geriatrics, CIOMS, CIOMS Working Groups, CIOMS Form, CDSCO (India) and Pharmacovigilance, D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements	**BSCR617_CO5:** Explain & Describe the role of pharmacogenomics in ADR	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR617_CO	3	1	2	3	2	-	2	1	2	-

1										
BSCR617_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR617_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR617_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR617_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR617_CO1	20
2	BSCR617_CO2	20
3	BSCR617_CO3	20

4	BSCR617_CO4	20
5	BSCR617_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR617_CO1	1,2,3,4,7	1,4,5
2	BSCR617_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR617_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR617_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR617_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books

- P Walker et al, An Introduction to Pharmacovigilance 2017
- T Doan et al, Pharmacovigilance: A Practical Approach, 2018
- Cobert, Cobert's Manual of Drug Safety and Pharmacovigilance, 2011

Internet:

1. http://www.who.int>areas_quality_safety_efficacy_phamvigilance
2. http://www.primevigilance.com
3. http://www.pharmatutor.org

Reference Material (Journals, Handout)

1. International Journal of Pharmacovigilance
2. Journal of Pharmacovgilance and Pharamcotherapeutics

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 618	Major (Depth)	CLINICAL DATA MAMANGEMENT	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Clinical Data Management Introduction to Clinical Data Management: Definition & types, CRF Design for Clinical Trial, Data Management Plan, GCDMP, Clinical data and its quality, Clinical data repositories, Data privacy, EDC system, 21 CFR part 11 compliance, Data management: Clinical Trial, Epidemiology, Pharmacogenomics	DEFINE, REMEMBER, DESCRIBE, Introduction to Clinical Data Management: Definition & types, CRF Design for Clinical Trial, Data Management Plan, GCDMP, Clinical data and its quality, Clinical data repositories, Data privacy, EDC system, 21 CFR part 11 compliance, Data management: Clinical Trial, Epidemiology, Pharmacogenomics	**BSCR618_CO1**: Define & explain the importance and process of clinical data management	**2**
Unit II: Data: Entry, Quality, Validation & Integrity Data clarification form, Patient diary and patient reported outcome, Remote data entry, Clinical data entry-Single	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Data clarification form, Patient diary and patient reported outcome, Remote data entry, Clinical data entry-Single	**BSCR618_CO2:** Describe the process of data validation	**2**

entry, Double entry, Data validation, programming & standards, data handling, data transfer, CDM presentations, Metrics for Clinical trials, Clinical trial database environment, Data Quality and Data Integrity, Assuring data quality, Measuring data quality, Data storage, Data entry process, Medical coding dictionary management and maintenance, Safety data management and reporting, Serious adverse event data reconciliation, Database closure, Clinical data archiving	entry, Double entry, Data validation, programming & standards, data handling, data transfer, CDM presentations, Metrics for Clinical trials, Clinical trial database environment, Data Quality and Data Integrity, Assuring data quality, Measuring data quality, Data storage, Data entry process, Medical coding dictionary management and maintenance, Safety data management and reporting, Serious adverse event data reconciliation, Database closure, Clinical data archiving		
Unit III: Case Record Form CRF Design, Elements of CRF, Electronic-CRF designing, data tracking from CRF, Electronic data capture, Types of reports generated, Study close out, CRF completion guidelines, clinical data archiving Medical Coding, SAE reconciliation, coding of adverse events, clinical data single entry-double entry, Six Sigma in Clinical Research	DEFINE, EXPERIMENT, DISCUSS CRF Design, Elements of CRF, Electronic-CRF designing, data tracking from CRF, Electronic data capture, Types of reports generated, Study close out, CRF completion guidelines, clinical data archiving Medical Coding, SAE reconciliation, coding of adverse events, clinical data	**BSCR618_CO3:** Explain & define the CRF design	**3**

	single entry-double entry, Six Sigma in Clinical Research		
Unit IV: IT in CDM & CDISC IT in clinical database management, Introduction to Clinical data management programs: DoCDat, Patient Profiles, OpenClinica, iDiary, CTMS, Databean, Geospiza, Clintrial, software validation CDISC- standards, Clinical Data Entry, Clinical Data Validation, Discrepancy Management, Query management,	DEFINE, DESCRIBE, IT in clinical database management, Introduction to Clinical data management programs: DoCDat, Patient Profiles, OpenClinica, iDiary, CTMS, Databean, Geospiza, Clintrial, software validation CDISC- standards, Clinical Data Entry, Clinical Data Validation, Discrepancy Management, Query management,	**BSCR618_CO4:** Understand & define the role of IT in CDM	**2**

Unit V: Quality Audits Quality Audit: Definition, types & procedures, standards, Audit trail & its role in authenticity of data, Audit plan, Audit by regulatory authorities, GMP, GDP & logistics, Preparing and delivering audit reports, good audit, product development & GxP Regulations	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Quality Audit: Definition, types & procedures, standards, Audit trail & its role in authenticity of data, Audit plan, Audit by regulatory authorities, GMP, GDP & logistics, Preparing and delivering audit reports, good audit, product development & GxP Regulations	**BSCR618_CO5:** Explain & Describe the role of audit in DM	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR618_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR618_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR618_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR618_CO 4	2	2	-	3	1	1	2	2	2	2

BSCR618_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes

8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR618_CO1	20
2	BSCR618_CO2	20
3	BSCR618_CO3	20
4	BSCR618_CO4	20
5	BSCR618_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR618_CO1	1,2,3,4,7	1,4,5

2	BSCR618_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR618_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR618_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR618_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

- Practical Guide to Clinical Data Management 3/E, CRC Press, 2011
- Management of Data in Clinical Trials, Willey, 2007.
- Medical Data Management: A Practical Guide, Springer, 2003.
- Pharmacogenomics methods and protocols, Federico innocenti, Humana press, 2005

Internet:

- National centre for biotechnology information, www.ncbi.nlm.nih.gov
- Medidata, http://www.mdsol.com/products/rave_capture.htm
- ClinPlus, http://www.clinplus.com/products/clinical-data-management/Drug Bank, www.drugbank.ca
- Progeny, http://www.progenygenetics.com/clinical/

3. Reference Material (Journals, Handout)

- Journal of Clinical Research
- Journal of Clinical Research & Bioethics
- Clinical Research & Regulatory Affairs

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 619	Major (Depth)	CLINICAL CASE STUDY	3	1	3	2	3	Nil

2. Syllabus

This course, being in the form of a case study, is unstructured, continues & no end term will be proposed. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the case study. Assisted by the internal supervisor, student develops a study design and plans for its timely execution. The student generates data and/or data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life case study with a problem solving approach.

3. Course Outcome

After completion of course, student will:
BSCR619_CO1: describe the of principles and hands on relevant techniques of biomedical research viz disease genesis, diagnostics & management
BSCR619_CO2: experiment and demonstrate the preparation of technical document(protocol, informed consent, clinical report form, clinical study report)
BSCR619_CO3: able to apply wet/dry lab methodologies and field activity
BSCR619_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular disease/disorder
BSCR619_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR619_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR619_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR619_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR619_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR619_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study

Hours	24	12	36	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	**CO**	**Marks**

1	BSCR619_CO1	20
2	BSCR619_CO2	20
3	BSCR619_CO3	20
4	BSCR619_CO4	20
5	BSCR619_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR619_CO1	1,2,3,4,7	1,4,5
2	BSCR619_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR619_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR619_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR619_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. **Reference Material (Journals, Handout)**
    - NCBI
    - CTRI
    - USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 620	Major (Depth)		3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	
Unit I INTRODUCTION Fundamentals of Economics: Scope & coverage of Health Economics, demand for Health Sciences; Health as an investment, population, Health & Economic Development.	DEFINE, REMEMBER, DESCRIBE, Fundamentals of Economics: Scope & coverage of Health Economics, demand for Health Sciences; Health as an investment, population, Health & Economic Development.	**BSCR620_CO1 :** Define & explain the elements of economics in healthcare	**1**
Unit II Mathematical tools Some Basic Graphical & Mathematical Techniques, Functions –Linear & non-linear. Straight Lines & Slopes, Marginal values & Incremental Ratios. Tools of Economics-Concepts of need, demand, supply & price in	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Some Basic Graphical & Mathematical Techniques, Functions –Linear & non-linear. Straight Lines & Slopes, Marginal values & Incremental Ratios. Tools of Economics-Concepts of need, demand, supply & price in	**BSCR620_CO2:** Describe the mathematical tools in economics research	**2**

Health Services	Health Services		
Unit III Economic Evaluation Methods & Techniques of Economic Evaluation of Health Programmes: Cost benefit & cost effective methods-output & input analysis. Market, monopoly, perfect & imperfect competition. Health Financing from various sources –Public , Private, TPA	DEFINE, EXPERIMENT, DISCUSS Methods & Techniques of Economic Evaluation of Health Programmes: Cost benefit & cost effective methods-output & input analysis. Market, monopoly, perfect & imperfect competition. Health Financing from various sources –Public , Private, TPA	**BSCR620_CO3:** Explain Experiment & define the elements of economic evaluation	**4**
Unit IV Economics of healthcare programmes Economics of Health Programmes for Nutrition, diet & population control, economics of abuse of tobacco & alcohol, environmental influences on health & its economic impact, economics of breast feeding. Economics of Communicable (STDs & Malaria) & non-communicable (IHD & Cancers) diseases	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS Economics of Health Programmes for Nutrition, diet & population control, economics of abuse of tobacco & alcohol, environmental influences on health & its economic impact, economics of breast feeding. Economics of Communicable (STDs & Malaria) & non-communicable (IHD & Cancers) diseases	**BSCR620_CO4:** Understand the economics of public health programs	**4**

Unit V Healthcare Budget Health Care Budget: purpose, types & practices in Indian context	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Health Care Budget: purpose, types & practices in Indian context	**BSCR620_CO5:** Explain & Describe the healthcare budget in Indian context	**2**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR620_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR620_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR620_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR620_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR620_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate

3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures

6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR620_CO1	20
2	BSCR620_CO2	20
3	BSCR620_CO3	20
4	BSCR620_CO4	20
5	BSCR620_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR620_CO1	1,2,3,4,7	1,4,5
2	BSCR620_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR620_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR620_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR620_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books

1. Ceri J Phillips (2008) Health Economics: An introduction for Health Professionals
2. AJ Culyer et al (2000) Handbook of Health Economics
3. L Guinness (2011) Introduction to Health Economics
4. Kernick D (2002) Getting Health Economics into Practice.

Internet

1. http://pmj.bml.com
2. https://www.bandolier.org.uk
3. http://healthknowledge.org.uk
4. http://who.int (WHO Health economics)

Reference Material (Journals, Hand-outs)

1. Health Economics
2. Journal of health Economics

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 621	Major (Depth)	Principles of Clinical Trial Management	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I Site initiation Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection, The roles and responsibilities of the following in CT: Sponsor, institution, Clinical Trial Coordinator: Clinical Investigator, Documents required at site, Site initiation and conduct activities: Protocol, CRF, ICD, Investigator brochure, Clinical trial agreement, ethics, Committee and regulatory approval, site-initiation visits	DEFINE, REMEMBER, DESCRIBE Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection, The roles and responsibilities of the following in CT: Sponsor, institution, Clinical Trial Coordinator: Clinical Investigator, Documents required at site, Site initiation and conduct activities: Protocol, CRF, ICD, Investigator brochure, Clinical trial agreement, ethics, Committee and regulatory approval, site-initiation visits	**BSCR621_CO1 :** Define & explain the process of site initiation	**1**

Unit II Site conduct Recruitment, IP/IMP/Pharmacy file receipt and storage, CT site master file, Databases, SOPs, Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections, independent data monitoring activities, Contingency planning to prepare for unexpected situations. Site interactions Review communication skills and concepts for interacting with site personnel; indicate key principles for establishing productive work relationship and strategies for handling site problems. Managing clinical supply/ laboratories, Review CRAs role and regulatory responsibilities for managing clinical supply laboratories and test articles accountability during the conduct of a trial. Address issues of test, noncompliance and the policy to prevent or address noncompliance.	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Recruitment, IP/IMP/Pharmacy file receipt and storage, CT site master file, Databases, SOPs, Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections, independent data monitoring activities, Contingency planning to prepare for unexpected situations. Site interactions Review communication skills and concepts for interacting with site personnel; indicate key principles for establishing productive work relationship and strategies for handling site problems. Managing clinical supply/ laboratories, Review CRAs role and regulatory responsibilities for managing clinical supply laboratories and test articles accountability during the conduct of a trial. Address issues of test,	**BSCR621_CO2:** Describe the process of conduct the trial in site	**2**

	noncompliance and the policy to prevent or address noncompliance.		
Unit III Site close-out activities Suspending and premature termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, Clinical study report, submission to ethics, committee and regulatory agency, publication of results	DEFINE, EXPERIMENT, DISCUSS Suspending and premature termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, Clinical study report, submission to ethics, committee and regulatory agency, publication of results	**BSCR621_CO3:** Explain & process of site close out activities	**3**
Unit IV The Protocol and Data Management Review the purpose of the protocol and key factors both from CRA and site prospective, and their role in handling protocol departures, types of data collection and regulatory requirement and industry standards for collecting retrieving and analyzing subject data. FDA inspections Review the purpose of FDA inspections, preparation for an FDA inspection, activity during an inspection, and	DEFINE, DESCRIBE, The Protocol and Data Management Review the purpose of the protocol and key factors both from CRA and site prospective, and their role in handling protocol departures, types of data collection and regulatory requirement and industry standards for collecting retrieving and analyzing subject data. FDA inspections Review the purpose of FDA inspections, preparation for an FDA inspection, activity	**BSCR621_CO4:** Understand the process of protocol and data management review	**2**

outcome of an inspection activity following FDA inspections Source Document Verification A brief review of basic data management concepts, discuss actual process of source documentation verification, addressing CRAs responsibilities, strategies and helpful hints for attacking data and problem resolution.	during an inspection, and outcome of an inspection activity following FDA inspections Source Document Verification A brief review of basic data management concepts, discuss actual process of source documentation verification, addressing CRAs responsibilities, strategies and helpful hints for attacking data and problem resolution.		
Unit V Training Orientation: Review role of monitor trainee including site objectives, pre-approval requirements for site visits, site visit planning, site visit expenses and expense forms, site visits SOPs and documentation and sign of for training to perform independent site visits. Interim visits Review the activities that take place during interim site visits and discuss the methodology for solving the most common problem that occur at investigative sites.	DEFINE, REMEMBER, DESCRIBE AND DISCUSS: Training Orientation: Review role of monitor trainee including site objectives, pre-approval requirements for site visits, site visit planning, site visit expenses and expense forms, site visits SOPs and documentation and sign of for training to perform independent site visits. Interim visits Review the activities that take place during interim site visits and discuss the methodology for solving the most common problem that	**BSCR621_CO5:** Explain & Describe the elements of training of site staff	**2**

Site close out audit and inspections Familarize new CRAs with activities that occur at the end of a trial and their responsibilities for completion of these activities	occur at investigative sites. Site close out audit and inspections Familarize new CRAs with activities that occur at the end of a trial and their responsibilities for completion of these activities		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR621_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR621_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR621_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR621_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR621_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping

1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	24	04	12	22

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments

4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR621_CO1	20
2	BSCR621_CO2	20
3	BSCR621_CO3	20
4	BSCR621_CO4	20
5	BSCR621_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR621_CO1	1,2,3,4,7	1,4,5
2	BSCR621_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR621_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR621_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7

5	BSCR621_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- A comprehensive and Practical Guide to Clinical Trials, D Shamley, B Wright
- Business Administration for Clinical Trials, R Jennifer Cavalieri
- Clinical Trial Project Management, M Robinson, H Korjonen

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int
- www.sciencedirect.com

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 650	Major (Depth)	RESEARCH PROJECT	1	1	3	1	2	Nil

2. Syllabus

This course, being in the form of a research project, is unstructured. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the research work. Assisted by the internal supervisor, and /or joint supervision with external guide, student develops a research design and plans for its timely execution. The student generates data and/or data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student**3.**

Course Outcome

After completion of course, student will:
BSCR650_CO1: describe the of principles and hands on relevant expertise of clinical research viz trial design, site management, regulatory affairs, GCP, CDM & management
BSCR650_CO2: experiment and demonstrate the preparation of technical document (protocol, informed consent, clinical report form, clinical study report)
BSCR650_CO3: able to apply experimental methods to the real life problems
BSCR650_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular clinical research
BSCR650_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR650_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR650_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR650_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR650_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR650_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study

Hours	12	12	36	02	06	04

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	**CO**	**Marks**

1	BSCR650_CO1	20
2	BSCR650_CO2	20
3	BSCR650_CO3	20
4	BSCR650_CO4	20
5	BSCR650_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR650_CO1	1,2,3,4,7	1,4,5
2	BSCR650_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR650_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR650_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR650_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 651	Major (Elective)	Epidemiology	2	2	6	2	4	Nil

Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I Introduction to Epidemiology Introduction & Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation	DESCRIBE, REMEMBER, RELATE Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, UNDERSTAND, RELATE, DESCRIBE Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation	BSCR651_CO1 Describe the epidemiology, philosophy and applications	2

of Epidemics and New Diseases, Biologic Spectrum of Disease, Surveillance of Community Health Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease.	of Epidemics and New Diseases, Biologic Spectrum of Disease, Surveillance of Community Health Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease		
Unit II Epidemiologic Data Analysis Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates Standardization of Death Rates, Rates for Maternal and Infant Health	IDENTIFY, ASSOCIATE, ANALYZE, EVALUATE, Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates, Standardization of Death Rates, Rates for Maternal and Infant Health	BSCR651_CO2 Analyze, Interpret & explain the epidemiology relationship with statistics	3
Unit III Epidemiologic Surveillance and Epidemic Outbreak Investigation Surveillance of Disease: Role of Surveillance, Creation of	CLASSIFY, PREDICT, SKETCH, ORDER, HYPOTHESIZE, PLAN Surveillance of Disease: Role	BSCR651_CO3 Hypothesize & Design the Disease Surveillance Model to identification of epidemic	3

Surveillance System, Methods and Functions of Disease Surveillance, Establishment of Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures	of Surveillance, Creation of Surveillance System, Methods and Functions of Disease Surveillance, Establishment of Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures	outbreak	
Unit IV Research Designs and Issues in Epidemiology Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological Studies, Observational Designs, Cohort Studies, Case-Control Studies, Nested Case-Control Studies, Randomized Controlled	DEFINE, DEMONSTRATE, APPLY, PREPARE, COMPARE, DEVELOP Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological Studies, Observational Designs, Cohort Studies, Case-Control Studies, Nested Case-	BSCR651_CO4 Design the Epidemiology Study	5

Clinical Trials, Randomized Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues	Control Studies, Randomized Controlled Clinical Trials, Randomized Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues		
Unit V Assessment of Risk and Benefit in Epidemiologic Studies Definition Of Study Groups, Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit Analysis, Application of Risk Measures to Counselling of Patients	**RECOGNIZE, CLASSIFY, CALCULATE, PRIORITIZE, ASSESS** Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit Analysis, Application of Risk Measures to Counselling of Patients	BSCR651_CO5 Assessment & Evaluation of risk in Epidemiological Studies	4

Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR651_CO 1	3	-	-	3	2	-	-	2	2	-
BSCR651_CO 2	3	3	2	1	2	2	3	2	3	3
BSCR651_CO 3	2	3	3	2	2	3	-	2	3	3
BSCR651_CO 4	3	3	2	2	3	2	2	2	3	3
BSCR651_CO 5	2	3	3	2	2	3	2	2	3	3

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR651_CO1	20
2	BSCR651_CO2	20
3	BSCR651_CO3	20
4	BSCR651_CO4	20
5	BSCR651_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR651_CO1	1,2,3,4,7	1,4,5
2	BSCR651_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR651_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR651_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR651_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

9. Bibliography and References

Text books

- High-Yield Biostatisitcs, Epidemiology and Public Health- AN Glaser
- Modern Epidemiology- Rothman, Greenland & Lash
- Biostatistics and Epidemiology: A Primer for Health and Biomedical Professionals- Smoller & Smoller
- Introduction to Epidemiology: Merrill

Internet

- WHO: Epidemiolgy http://www.who.int/topics/epidemiology/en/
- The BMJ http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/1-what-epidemiology
- CDC Epidemiology http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section1.html

Reference Material (Journals, Hand-outs)

Journals-

- Epidemiology- http://journals.lww.com/epidem/Pages/default.aspx
- Journal of Epidemiology & Community Health http://jech.bmj.com/

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 653	Major (Elective)	BUSINESS DEVELOPMENT	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research work. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of business development for the clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:
BSCR653_CO1: describe the principles and hands on relevant expertise of business development in clinical trial.
BSCR653_CO2: experiment and demonstrate the preparation of technical document such as business proposal for the clinical trial
BSCR653_CO3: able to apply experimental business methods to the real life problems
BSCR653_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular clinical trial business development

BSCR653_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR653_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR653_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR653_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR653_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR653_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-

						Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR653_CO1	20
2	BSCR653_CO2	20
3	BSCR653_CO3	20
4	BSCR653_CO4	20
5	BSCR653_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR653_CO1	1,2,3,4,7	1,4,5
2	BSCR653_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR653_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR653_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR653_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 652	Major (Elective)	CLINICAL TRIAL MANAGEMENT	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:

BSCR652_CO1: describe the of principles and hands on relevant expertise of clinical trial viz trial design, site management, regulatory affairs, GCP, CDM & management

BSCR652_CO2: experiment and demonstrate the preparation of technical document: SOP, protocol, informed consent, clinical report form, clinical study report)

BSCR652_CO3: able to apply experimental methods to the real life problems

BSCR652_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular clinical trial

BSCR652_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR652_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR652_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR652_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR652_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR652_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale

--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR652_CO1	20
2	BSCR652_CO2	20
3	BSCR652_CO3	20
4	BSCR652_CO4	20
5	BSCR652_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR652_CO1	1,2,3,4,7	1,4,5
2	BSCR652_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7

3	BSCR652_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR652_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR652_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	**Category**	**Course title**	**Scheme**				**Credits**	**Pre-requisite as per NEP 2020**
			L	**T**	**P**	**O**		
BSCR 654	Major (Elective)	CLINCAL TRIAL DATA ANALYST	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research work. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of data analyst for the clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:
BSCR654_CO1: describe the principles and hands on relevant expertise of data analysis in clinical trial.
BSCR654_CO2: experiment and demonstrate the preparation of technical document such as data validation & analysis methods for the clinical trial
BSCR654_CO3: able to apply experimental methods to the real life data sets
BSCR654_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular data analysis
BSCR654_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR654_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR654_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR654_CO 3	2	2	2	3	1	1	2	2	2	-

BSCR654_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR654_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams

3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR654_CO1	20
2	BSCR654_CO2	20
3	BSCR654_CO3	20
4	BSCR654_CO4	20
5	BSCR654_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR654_CO1	1,2,3,4,7	1,4,5
2	BSCR654_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR654_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR654_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR654_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 656	Major (Elective)	MEDICAL CODING AND DATABASE DESIGN	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research work. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of medical coding & database design for the clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information, and employs methods to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:
BSCR656_CO1: describe the principles and hands on relevant expertise of database design & medical coding in clinical trial.
BSCR656_CO2: experiment and demonstrate the preparation of supporting technical document for the development of database and coding dictionary
BSCR656_CO3: able to apply DBs design methods to the real life case studies
BSCR656_CO4: learn and understand the in depth knowledge of the progress in the chosen area of clinical research

BSCR656_CO5: apply and demonstrate the knowledge of SW

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3

BSCR656_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR656_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR656_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR656_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR656_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study

Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	**CO**	**Marks**

1	BSCR656_CO1	20
2	BSCR656_CO2	20
3	BSCR656_CO3	20
4	BSCR656_CO4	20
5	BSCR656_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR656_CO1	1,2,3,4,7	1,4,5
2	BSCR656_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR656_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR656_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR656_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 657	Major (Elective)	IPR & REGULAOTRY AFFAIRS	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research work. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of IP for the clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information, and employs methods to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:
BSCR657_CO1: describe the principles and hands on relevant expertise of IP & regulatory affairs in clinical trial.
BSCR657_CO2: experiment and demonstrate the preparation of supporting technical document such as SOPs, Protocol etc the clinical trial
BSCR657_CO3: able to apply IP methods to the real life case studies
BSCR657_CO4: learn and understand the in depth knowledge of the progress in the chosen area of clinical research

BSCR657_CO5: apply and demonstrate the knowledge of SW

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR657_CO	3	1	2	3	2	-	2	1	2	-

1										
BSCR657_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR657_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR657_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR657_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

9. Home assignments
10. Mid-Term Exams
11. End-Term Exam
12. Class Attendance
13. Program implementation and laboratory written reports
14. Portfolio Oral Presentation
15. Quizzes
16. Practical Exam cum Viva

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle
12. Video lectures
13. Demonstrations
14. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR657_CO1	20

2	BSCR657_CO2	20
3	BSCR657_CO3	20
4	BSCR657_CO4	20
5	BSCR657_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR657_CO1	1,2,3,4,7	1,4,5
2	BSCR657_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR657_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR657_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR657_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 658	Major (Elective)	CLINICAL AUDITOR	2	2	6	2	4	Nil

2. Syllabus

This course, being in the form of a research work. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the domain of auditing for the clinical trial. Student will be assisted by the internal supervisor, and /or joint supervision with external guide, where required. The student will generates data and/or other relevant information, and employs methods to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student

3. Course Outcome

After completion of course, student will:
BSCR658_CO1: describe the principles and hands on relevant expertise of auditing in clinical trial.
BSCR658_CO2: experiment and demonstrate the preparation of supporting technical document required for the auditing of a clinical trial
BSCR658_CO3: able to apply auditing methods to the real life case studies
BSCR658_CO4: learn and understand the in depth knowledge of the progress in the chosen area of clinical research

BSCR658_CO5: apply and demonstrate the knowledge of SW in auditing

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR658_CO 1	3	1	2	3	2	-	2	1	2	-

BSCR658_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR658_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR658_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR658_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR658_CO1	20
2	BSCR658_CO2	20

3	BSCR658_CO3	20
4	BSCR658_CO4	20
5	BSCR658_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR658_CO1	1,2,3,4,7	1,4,5
2	BSCR658_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR658_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR658_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR658_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI

- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 700	Major (Research)	DISSERTATION	1	1	24	10	12	Nil

2. Syllabus

This course, being in the form of a research project, is unstructured. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the research work. Assisted by the internal supervisor, and /or joint supervision with external guide, student develops a research design and plans for its timely execution. The student generates data and/or data mines, and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life projects with a problem solving approach. Preferably the topic may be related to elective courses opted by student**3.**

Course Outcome

After completion of course, student will:
BSCR700_CO1: describe the of principles and hands on relevant expertise of clinical research viz trial design, site management, regulatory affairs, GCP, CDM & management
BSCR700_CO2: experiment and demonstrate the preparation of technical document (protocol, informed consent, clinical report form, clinical study report)
BSCR700_CO3: able to apply experimental methods to the real life problems
BSCR700_CO4: learn and understand the in depth knowledge of the progress in the chosen area of particular clinical research

BSCR700_CO5: apply and demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR700_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR700_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR700_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR700_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR700_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	12	12	288	24	24	72

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

9. Home assignments
10. Mid-Term Exams
11. End-Term Exam
12. Class Attendance
13. Program implementation and laboratory written reports
14. Portfolio Oral Presentation
15. Quizzes
16. Practical Exam cum Viva

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle
12. Video lectures
13. Demonstrations
14. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR700_CO1	20
2	BSCR700_CO2	20
3	BSCR700_CO3	20
4	BSCR700_CO4	20
5	BSCR700_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR700_CO1	1,2,3,4,7	1,4,5
2	BSCR700_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR700_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR700_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR700_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSBT501	Major (Fundamental)	Biostatistics	3	1	2		3	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit 1: Introduction to Biostatistics	Definition and scope of biostatistics. Role of biostatistics in health and life sciences research. Role of biostatistics in health and life sciences research. Data Organization and Presentation. Calculation and interpretation of mean, median, and mode. Simple random sampling, stratified sampling, and cluster sampling.	BSBT 501_CO1: Understand the role of biostatistics in health and life sciences research.	**2**
Unit 2: Descriptive Statistics and Data Presentation	Frequency Distributions and Histograms. Construction and interpretation of frequency distributions. Percentiles, quartiles, and deciles. Box plots and scatter plots for data visualization.	BSBT 501_CO2: Apply methods to construct and interpret frequency distributions and data visualizations.	**3**
Unit 3: Probability and Probability Distributions	Basic Probability Concepts. Basic Probability Concepts. Normal Distribution. Sampling Distribution and Central Limit Theorem. Other Probability Distributions.	BSBT 501_CO3: Understand and analyze basic probability concepts and various probability distributions.	**4**
Unit 4: Statistical Inference	Estimation and Confidence Intervals. Hypothesis Testing. Hypothesis Testing. Hypothesis Testing.	BSBT 501_CO4: Demonstrate proficiency in statistical inference, estimation, confidence intervals, and hypothesis testing techniques.	**3**
Unit 5: Analysis of Biostatistical Data	Hypothesis Testing. Hypothesis Testing. Survival Analysis. Data Analysis using Statistical Software.	BSBT 501_CO5: Apply hypothesis testing and survival analysis techniques, and perform data analysis using statistical software.	**3**

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

Course Delivery Plan

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSBT501_CO 1	3			3	2	1	2	1	2	-
BSBT501_CO 2	2	3	2	3	2	2	2	2	-	-
BSBT501_CO 3	2	2	2	2	1	-	-	2	2	-
BSBT501_CO 4	2	2	2	2	1	-	-	2	2	2
BSBT501_CO 5	1	-	-	1	-	-	-	2	-	-

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

10. Home assignments
11. Mid-Term Exams
12. End-Term Exam
13. Class Attendance
14. Program implementation and laboratory written reports
15. Portfolio Oral Presentation
16. Quizzes
17. Practical Exam cum Viva

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle
12. Video lectures
13. Demonstrations
14. Virtual Labs

Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSBT501_CO1	20
2	BSBT501_CO2	20
3	BSBT501_CO3	20
4	BSBT501_CO4	20
5	BSBT501_CO5	20

1. Bibliography and References

Prescribed Texts:

Title: "Artificial Intelligence in Healthcare: The Future is Now" ***Author: Susan Culican, PhD Publisher: Medical AI Press Year: 2022.***

Title: "Artificial Intelligence in Healthcare: The Future is Now" ***Author: Susan Culican, PhD Publisher: Medical AI Press Year: 2022.***

Reference Books:

- "Introduction to Biostatistics" by Robert R. Sokal and F. James Rohlf
- "Biostatistics: A Foundation for Analysis in the Health Sciences" by Wayne W. Daniel and Chad L. Cross
- "Biostatistics: The Bare Essentials" by Geoffrey R. Norman and David L. Streiner
- "Principles of Biostatistics" by Marcello Pagano and Kimberlee Gauvreau
- "Applied Biostatistics for the Health Sciences" by Richard J. Rossi and Myra L. Samuels

- "Design and Analysis of Experiments in the Health Sciences" by Bryan F.J. Manly
- "Statistical Methods in Epidemiology" by Elizabeth S. Mostofsky and Thomas P. Ryan

Internet Reference:

- National Institutes of Health (NIH) Biostatistics Research - https://www.nih.gov/research-training/medical-research-initiatives/biostatistics-research
- World Health Organization (WHO) - Biostatistics - https://www.who.int/healthinfo/statistics/biostatistics/en/
- The Biostatistics Collaboration of Australia (BCA) - https://biostats.org.au/
- American Statistical Association - Biometrics Section - https://www.amstat.org/ASA/Your-Career/Biometrics-Section.aspx
- Johns Hopkins Bloomberg School of Public Health - Biostatistics Resources - https://www.jhsph.edu/departments/biostatistics/resources/index.html

Reference Material (Journals, Handout)

1. **National Institutes of Health (NIH) Biostatistics Research** - https://www.nih.gov/research-training/medical-research-initiatives/biostatistics-research
2. **World Health Organization (WHO) - Biostatistics** - https://www.who.int/healthinfo/statistics/biostatistics/en/
3. **The Biostatistics Collaboration of Australia (BCA)** - https://biostats.org.au/
4. **American Statistical Association - Biometrics Section** - https://www.amstat.org/ASA/Your-Career/Biometrics-Section.aspx
5. **Johns Hopkins Bloomberg School of Public Health - Biostatistics Resources** - https://www.jhsph.edu/departments/biostatistics/resources/index.html

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSBT 517	Major (Fundamental)	IPR	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding COs	Bloom's Taxonomy Level
Unit 1: Intellectual Property Rights: Introduction, History	DEFINE AND REMEMBER Introduction to Intellectual Property:. Definition, Scope and Rights covered under: Copyright, Trademark, Geographical indication, Industrial Design & Patents International organizations and Treaties (pre- TRIPs era): Paris, Berne and Rome convention, Budapest Treaty. CBD, UPOV convention. WIPO, GATT, FAO, UNCTAD, WTO Framework and the TRIPs. Patent Act of 1970	**BSBT505_CO1:** Define Intellectual Property Rights (IPR) in the context of biotechnology and describe their significance in research and innovation.	**1**

Unit 2:Ethics and Values in IPR	REMEMBER AND DEFINE AND EVALUATE IPR and ethics: positive and negative aspects of IPR; Societal responsibility; Avoiding unethical practices; Economic, social and environmental benefits of IPR in biotechnology industry; Voluntary adoption of genetically modified strategies in India Replication, Randomization & Local control, Components of research plan	**BSBT505_CO2:** Evaluate the ethical implications of IPR in biotechnology, including both positive and negative aspects.	**4**
Unit 3:IPR in Biotechnology	ANALYZE AND EXAMINE Patentability criteria in Biotechnology, Distinction between discovery and innovation in Biotechnology. Traditional knowledge, IPR and Benefit sharing Indigenous knowledge and its appropriation IPR & Traditional Medicine, Private vis-à-vis community based ownership, Biopiracy, Breeders vis-à-vis Farmers rights, Life form patenting (technical and ethical	**BSBT505_CO3:** Examine the patentability criteria in biotechnology and differentiate between discoveries and innovations in this field.	**3**

	issues) Representative case studies giving examples of patents and technology transfer, access and affordability of medicines in India.		
Unit 4:Regulatory Affairs for Biopharmaceutical Industries in India	Regulatory Affairs for Biopharmaceutical Industries in India The Drugs and Cosmetics Act, The Narcotics Drugs and Psychotropic Substances Act, Medicinal and Toilet Preparations (Excise Duties) Act, 1955, Drugs (Price Control) Order in force, Copy Right Act, Trade Mark Act, and Biodiversity Act, The Drugs and Magic Remedies Act, 1955. Prevention of Cruelty to Animals Act, The Environmental Protection Act.	**BSBT505_CO4:** Analyze representative case studies of patents and technology transfer in biotechnology and evaluate their impact on access to medicines.	**4**
Unit 5: Global Agencies in IPR & Regulatory Affairs	ANALYZE AND EVALUATE World intellectual Property organization (WIPO), Trade Related intellectual Property (TRIPS), WIPO Administered Treaties on international Registration Systems, Patent Co-operation Treaty (PCT), unfair competition, Protection of	**BSBT505_CO5:** Evaluate the significance of World Intellectual Property Organization (WIPO), Trade-Related Intellectual Property (TRIPS), and WIPO-administered treaties on international registration systems, such as the Patent Cooperation Treaty (PCT).	**5**

	New Varieties of Plants.		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
CO 1	3	2		3	2			1	2	-
CO 2	2	3	2	3		2	2	2	-	-
CO 3	2	2	2	2	1	-	-	2	2	-
CO 4	2	2	3	1	1	-	1	2	2	2
CO 5	3	1	1	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study

Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams
3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

15. Blackboard Teaching
16. Power point slides
17. Practice assignments
18. LMS Moodle
19. Video lectures
20. Demonstrations
21. Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSBT517_CO1	20
2	BSBT517_CO2	20
3	BSBT517_CO3	20
4	BSBT517_CO4	20
5	BSBT517_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSBT517_CO1	1,2,3,4,7	1,4,5,7
2	BSBT517_CO2	1.2,3,4,5,8	1,3,4,5,6,7
3	BSBT517_CO3	1,2,3,4,5,8	1,2,3,4,5,6,7
4	BSBT517_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSBT517_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

9. Bibliography and References

Prescribed Texts:

- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by US-FDA. 2nd Edition, published by Informa Healthcare. ISBN 1420073540
- Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, by Gary Walsh, John J. Tobin published by Wiley-VCH Verlag GmbH. ISBN 978352731877.

Internet Reference:

- Journal of Intellectual Properties Rights
- The WIPO Journal
- European Patent Bulletin
- www.wipo.int 5. www.ficciipcourse.i

Reference Material (Journals, Handout)

- Nature
- Science
- PNAS
- Journal of Intellectual Property Rights

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSBT 521	Major (Fundamental)	Molecular Immunodiagnostics	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding COs	Bloom's Taxonomy Level
UNIT I: Molecular Diagnostics methods	UNDERSTAND, REMEMBER AND DEMONSTRATE DNA Amplification techniques: Allele-specific mutation detection by PCR-ARMS, PCR-ASO, Loop mediated amplification (LAMP). Enzymatic cleavage methods to Identify mutation (RFLP, PCR-RFLP). Oligonucleotide ligation assay (OLA), Strand displacement amplification (SDA). Automations in molecular diagnostics. Primer designing for mutation detection by PCR. Mutation detection by Single Strand Conformation Polymorphism (SSCP) and Heteroduplex Analysis, Denaturing Gradient Gel Electrophoresis (DGGE). Real-Time Polymerase Chain Reaction (RT-PCR) for quantitative determination. Microarrays. Specimen collection for molecular diagnostics; types of samples, collection methods, sample storage, Preservation and storage, Transport. Molecular diagnostics in Human Forensics. Use of Locus-Specific	**BSBT521_CO1:** Demonstrate an understanding of various DNA amplification techniques and their applications in mutation detection.	**2**

	Databases in Molecular Diagnostics.		
UNIT II: Molecular Diagnosis of Infectious diseases, parasites and cancer	REMEMBER AND ANALYZE Microbial genetic database for pathogenic diagnosis. Molecular assay of selected infectious Diseases. Parasitic DNA barcoding. Application of molecular database and techniques in cancer diagnosis Oncogene and tumour suppressor gene mutations. Virus detection involved in cancer Universal markers for species & strain identification & DNA based diagnosis. Southern blotting technique, DNA sequencing, Chromosome walking. Latest molecular techniques for Diagnosis.	**BSBT521_CO2:** Explore the use of microbial genetic databases for pathogenic diagnosis and the molecular assays of selected infectious diseases.	**2**
UNIT III : Immunological diagnostic methods	UNDERSTAND, REMEMBER Introduction to immunological techniques , Ag-Ab precipitin reaction, Agglutination reaction and their use in diagnostics; Immunodiffusion, immunoelectrophoresis, Rocket immunoelectrophoresis. Agglutination based techniques, Immunoprecipitation, Immunofluorescence, ELISA (Dot ELISA, sandwich ELISA), ELISPOT, Skin test. Serological typing of immuno markers, immunophenotyping,	**BSBT521_CO3:** Familiar with various immunological techniques, such as immunodiffusion, ELISA, and immunofluorescence, and their roles in diagnostics.	**2**

	immunohistochemistry, Pregnancy testing and blood typing.		
UNIT IV: Case studies of Disease diagnostics	REMEMBER AND ANALYZE Case studies of disease diagnostics using molecular & immunological techniques: Cancer diagnostics (Breast, Leukemias) Pathogenic diseases diagnostics (HPV, HIV), metabolic disorders diagnostics. Cardiac disorders. Genetic diseases diagnostics : Mendelian & Non mendelian. Role of epidemiological database in developing molecular markers for disease diagnostics.	**BSBT521_CO4:** Analyze case studies related to molecular and immunological techniques in cancer diagnostics, pathogenic diseases, metabolic disorders, and cardiac disorders.	**4**
UNIT V: Radiotracer technology in diagnostics	REMEMBER, UNDERSTAND AND DEMONSTRATE Application of radioisotopes in biology. Properties and units of radioactivity. Radioactive isotopes and half life. Measurement of radioactivity: (basic knowledge) GM Counter, gamma counter, Liquid scintillation counter. Tracer techniques (basic knowledge): Autoradiography, radioimmunoassay (RIA). Pitfalls of immunoassays,	**BSBT521_CO5:** Recognize the importance of safety rules and precautions when handling radioisotopes and hazardous chemicals in the laboratory.	**3**

	radioreceptor assay (RRA). Safety rules in handling of radioisotopes and hazardous chemicals		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
CO 1	3	3		3	2			1	2	-
CO 2	2		2	3		2	2	2	-	-
CO 3	2		2	2	1	2	-	2	2	-
CO 4	2		2	2	1	2	-	2	2	2
CO 5	1	-	2	1	2	-	-	2	2	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

- Home assignments
- Mid-Term Exams
- End-Term Exam
- Class Attendance
- Program implementation and laboratory written reports
- Portfolio Oral Presentation
- Quizzes
- Practical Exam cum Viva

6. Teaching Tools

- Blackboard Teaching
- Power point slides
- Practice assignments
- LMS Moodle
- Video lectures
- Demonstrations
- Virtual Labs

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSBT521_CO1	20
2	BSBT521_CO2	20
3	BSBT521_CO3	20
4	BSBT521_CO4	20
5	BSBT521_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSBT521_CO1	1,2,3,4,7	1,4,5,6
2	BSBT521_CO2	1.2,3,4,5, 6,8	1,3,4,5,7
3	BSBT521_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSBT521_CO4	1,2,3,4,5,8	1,2,3,4,5,7
5	BSBT521_CO5	1,2,3,4,5,8	1,2,3,4,5,7

10. Bibliography and References

Text books:

- Burns DE - Fundamentals of Molecular Diagnostics, Saunders publication, Elsevier, 2009.
- Mepham B Bioethics - an introduction for the bioscience Oxford . 2008
- Nunnually Briank, Analytical Techniques in DNA sequencing, Taylor and Francis,New Delhi, 2009
- Freifelder David, Essentials of Molecular Biology,2nd, Panima Publisher,New Delhi, 1996
- Watson James D, Molecular Biology the gene, 5th, Pearson,New Delhi,2009
- Helen M Kingston, Consultant Clinical Geneticist, Regional Genetic Service, St Mary's Hospital, Manchester, UK , ABC OF CLINICAL GENETICS, by; Third edition,
- S J Ianacimuthu S ed, Methods in Biotechnology,2nd ed,Elite Publishing House, New Delhi, 2010
- Hughes S ed.PCR methods express, Scion Publishing Delhi 2007.
- . Kuby- Immunology (4th Edition) by R. A. Goldsby, T.J. Kindt, B.A. Osborne.
- 2. Essentials of Immunology (6th Edition): Ivan Riot- Blakswell Scientific Publications, Oxford, 1988.

Journals:

i. Biotech News.
ii. The journal of molecular diagnostics
iii. BMC molecular biology
iv. Science
v. Nature
vi. Proceedings of the National Academy of Sciences U S A (PNAS)

Internet Reference:

- http://evolve.elsevier.com/Burns/molecular
- www.ncbi.nlm.nih.gov
- www.ensemble.org.
- http://www.biotechnologyeducation.isonlinehere.com.au/resource/Agarose%20Gel%20Electrophoresis%20Using%20Dyes.pdf
- http://delloyd.50megs.com/moreinfo/buffers2.html#top

Reference Material (Journals, Handout)

- Nature
- Science
- PNAS
- Clinical Endocrinology
- AUK
- Current Science

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSBT 505	Major (Fundamental)	Research Methodology	3	1	2		3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding COs	Bloom's Taxonomy Level
Unit I: Research Methodology Introduction to Research, Research: Meaning, Objectives & Motivation, Research: types, approaches & significance, Difference between methods &	REMEMBER and DISCUSS Introduction to Research, Research: Meaning, Objectives & Motivation, Research: types, approaches & significance, Difference between methods & methodology, criteria for	**BSBT505_CO1:** Understand and differentiate between research methods and methodology.	**2**

methodology, criteria for good research	good research.		
Unit II: Problem identification, Research Design & Research Plan Defining a research problem, How to select the problem, Statement of the problem, literature review, idea development, need of research design, feature for good design, variable, controls, research hypothesis, exploratory research, descriptive and diagnostic research, Principles of experiment design: Replication, Randomization & Local control, Components of research plan	UNDERSTAND, DEFINE Defining a research problem, How to select the problem, Statement of the problem, literature review, idea development, need of research design, feature for good design, variable, controls, research hypothesis, exploratory research, descriptive and diagnostic research, Principles of experiment design: Replication, Randomization & Local control, Components of research plan	**BSBT505_CO2:** Understand and define a research problem.	**2**
Unit III: Sampling Design, Data Collection & Data Analysis Census & survey techniques, Types of sampling, Sample size estimation, Measurement scales: nominal, ordinal, interval, ratio, Error, Bias & Precision, Test of validity, Reliability, Data collection & generation: Survey, wet lab exp, Dry lab exp, Data	ANALYSE and DISCUSS: Census & survey techniques, Types of sampling, Sample size estimation, Measurement scales: nominal, ordinal, interval, ratio, Error, Bias & Precision, Test of validity, Reliability, Data collection & generation: Survey, wet lab exp, Dry lab exp, Data mining, Data analysis: Coding, Classification, Descriptive	**BSBT505_CO3:** Analyse various methods of data collection.	**4**

mining, Data analysis: Coding, Classification, Descriptive statistics, Correlation & Regression, Test of hypothesis, Parametric & Non Parametric test, Biostatisitcs techniques	statistics, Correlation & Regression, Test of hypothesis, Parametric & Non Parametric test, Biostatisitcs techniques		
Unit IV: Writing and Presentation Interpretation of results, Report writing, Reference writing, Citation, Paper writing & communication, Paper presentation, Impact factor and Citation index, Intellectual property right, Plagiarism	ANALYSE AND DISCUSS: Interpretation of results, Report writing, Reference writing, Citation, Paper writing & communication, Paper presentation, Impact factor and Citation index, Intellectual property right, Plagiarism	**BSBT505_CO4:** Analyse, write and present results in a report.	**4**
Unit V: IT in Research Introduction to IT in research, Databases: Bioinformatics, Literature, Bibliographic, Search engines, Reference manager, Data analysis tools, Fundamentals of Chemistry Fundamentals of Chemistry	DISCUSS, ANALYSE and APPLY Introduction to IT in research, Databases: Bioinformatics, Literature, Bibliographic, Search engines, Reference manager, Data analysis tools,	**BSBT505_CO5:** Analyse and apply IT in research.	**4**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
CO 1	3			3	2			1	2	-

CO 2	2	3	2			2	2	2	-	-
CO 3	2	2	2	2	1	-	-	2	2	-
CO 4	2	2	2	2	1	-	-	2	2	2
CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	36	12	12	06	18	24

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

- Home assignments

- Mid-Term Exams
- End-Term Exam
- Class Attendance
- Program implementation and laboratory written reports
- Portfolio Oral Presentation
- Quizzes
- Practical Exam cum Viva

6. Teaching Tools

- Blackboard Teaching
- Power point slides
- Practice assignments
- LMS Moodle
- Video lectures
- Demonstrations
- Virtual Labs

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSBT505_CO1	20
2	BSBT505_CO2	20
3	BSBT505_CO3	20
4	BSBT505_CO4	20

5	BSBT505_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSBT505_CO1	1,2,3,4,7	1,4,5
2	BSBT505_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSBT505_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSBT505_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSBT505_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

11. Bibliography and References

Prescribed Texts:

- C.R. Kothari, Research Methodology Methods and Techniques,
- Bendat &Piersol, Random data: Analysis and Measurement Procedures, Wiley Interscience.

Internet Reference:

- NCBI, www.ncbi.nlm.nih.gov
- MEGA, http://www.megasoftware.net/
- eGradeSchool, http://www.egradschool.edu.au/whategsaoffe/researchmeth.jsp

Reference Material (Journals, Handout)

- Nature

- Science
- PNAS
- Clinical Endocrinology
- AUK
- Current Science

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 622	Major (Fundamental)	AI in Healthcare	3	1	3	2	3	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit 1: Introduction to AI in Healthcare	UNDERSTAND, REMEMBER AND EXPLAIN Overview of Artificial Intelligence (AI) in Healthcare, Definition of AI and its significance in the healthcare industry.	CO1_Explain the fundamental concepts and principles of artificial intelligence as applied in the healthcare industry.	**2**
Unit 2: AI Applications in Medical Imaging	REMEMBER, UNDERSTAND AND APPLY AI Applications in Medical Imaging, AI Applications in Medical Imaging, Overview of various medical imaging techniques. Image Preprocessing and Feature Extraction techniques	CO2_understand and Apply how AI can aid in medical diagnosis, including pattern recognition and decision support systems.	**3**
Unit 3: AI-Assisted Diagnostics	UNDERSTAND AND APPLY Diagnostic AI Algorithms, Understanding the role of AI in disease diagnosis and prognosis. Machine learning models for clinical decision support. AI in Pathology and Histopathology AI applications in analyzing tissue samples and identifying cellular patterns. Challenges and limitations of AI-based pathology diagnostics.	CO3_Understand Apply and Describe how AI can aid in medical diagnosis, including pattern recognition and decision support systems.	**3**
Unit 4: AI for Drug Discovery and Personalized Medicine	UNDERSTAND AND APPLY Drug Discovery Process and ChallengesOverview of the drug development pipeline. Role of AI in accelerating drug discovery and reducing costs. AI in Drug Design and Virtual Screening Generative models and de novo drug design. Virtual screening techniques using AI algorithms. Precision Medicine and AI Personalized treatment approaches based on genomic data. AI-driven patient stratification for targeted therapies.	CO4_Explain how AI is utilized in drug discovery processes, including drug design and virtual screening.	**3**

Unit 5: AI and Healthcare Management	REMEMBER AND ANALYZE AI in Healthcare Resource Management Optimizing hospital resources using predictive analytics. AI-driven patient flow management.	CO5_Analyze the applications of AI in healthcare management, including resource optimization and predictive analytics.	**4**

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR622_CO 1	3			3	2			1	2	-
BSCR622_CO 2	2	3	2			2	2	2	-	-
BSCR622_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR622_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR622_CO 5	1	-	-	1	-	-	-	2	-	-

Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	**Course Outcomes**	**Assessment Tools**	**Teaching Tools**
1	BSCR622_CO1	1,2,3,4,7	1,4,5

2	BSCR622_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR622_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR622_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR622_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

- Home assignments
- Mid-Term Exams
- End-Term Exam
- Portfolio Oral Presentation
- Class Activity

6. Teaching Tools

- Blackboard Teaching
- Power point slides
- Practice assignments
- LMS Moodle

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR622_CO1	20
2	BSCR622_CO2	20
3	BSCR622_CO3	20
4	BSCR622_CO4	20
5	BSCR622_CO5	20

2. Bibliography and References

Prescribed Texts:

- **Title: "Artificial Intelligence in Healthcare: The Future is Now"** ***Author: Susan Culican, PhD Publisher: Medical AI Press Year: 2022.***

- **Title: "Artificial Intelligence in Healthcare: The Future is Now"** ***Author: Susan Culican, PhD Publisher: Medical AI Press Year: 2022.***

Reference Books:

- Title: "Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again" *Author: Eric Topol, MD Publisher: Basic Books Year: 2019.*
- Title: "Artificial Intelligence in Medicine" *Editors: Adam Bohr, Alex Grabner, Robin Hill, Ronald R. Yager Publisher: Springer Year: 2020.*
- Title: "Machine Learning Techniques for Medical Image Analysis" *Authors: Zhonghua Sun, Xiaodong Zhang Publisher: Academic Press Year: 2020.*
- Title: "Data Science for Healthcare: Methodologies and Applications" *Authors: Daniel D. Gutierrez, Ph.D., Mia Chang, Ph.D. Publisher: Apress Year: 2022.*

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

Reference Material (Journals, Handout)

Journal of Medical Internet Research (JMIR)
Nature Medicine
IEEE Journal of Biomedical and Health Informatics (JBHI)

Journal of Healthcare Informatics Research (JHIR)
BMC Medical Informatics and Decision Making
Journal of Artificial Intelligence in Medicine

2. Syllabus Unit-Wise

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 601	Major (Fundamental)	Clinical Research: Fundamentals & Principals	3	1	3	2	3	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction to Clinical Research Definition, History: Galen experiments, James Lind experiments, Concept of randomization, Tuberculosis, Streptomycin study, Tuskegee Experiments, Nazi Experiment, Nuremberg code, Helsinki Declaration, Thalidomide study**,** Belmont Report, Current scenario of Clinical research in India, New career opportunities in clinical research, Different area of Clinical research: Clinical trials, Clinical Data management, Bioequivalence & bioavailability, Quality assurance, Medical writing, Pharmacovigilance & their responsibilities	REMEMBER History: Galen experiments, James Lind experiments, Concept of randomization, Tuberculosis, Streptomycin study, Tuskegee Experiments, Nazi Experiment, REMEMBER, DESCRIBE Nuremberg code, Helsinki Declaration, Thalidomide study**,** Belmont Report, EXPLAIN AND DISCUSS Current scenario of Clinical research in India, New career opportunities in clinical research, Different area of Clinical research: Clinical trials, Clinical Data management, Bioequivalence & bioavailability, Quality assurance, Medical writing, Pharmacovigilance & their responsibilities	**BSCR601_CO1 :** Describe the historical development & recognize the social impact in Clinical Research	**1**

Unit II: Drug Development Process (Clinical Research) High throughput screening (HTS), Lead optimization, target-centered drug design, Problems in extrapolating data from animals to humans, Concept of *in silico* drug designing, Concept of Pharmacogenomics	UNDERSTAND: High throughput screening (HTS), Lead optimization, target-centered drug design, DEFINE, DESCRIBE Problems in extrapolating data from animals to humans, Concept of *in silico* drug designing, Concept of Pharmacogenomics	**BSCR601_CO2:** Demonstrate & explain the drug development process in clinical research	**2**
Unit III: Formulation Development Introduction to different formulations, advantages and disadvantages of common formulations, Introduction to manufacturing of drugs and Good Manufacturing Practices (GMP), Quality assurance and quality control during manufacturing a drug, Biopharmaceutical classification on drugs	APPLY: Introduction to different formulations, advantages and disadvantages of common formulations, Introduction to manufacturing of drugs and Good DEMONSTRATE, DISCUSS Manufacturing Practices (GMP), Quality assurance and quality control during manufacturing a drug, DEFINE, DEMONSTRATE Biopharmaceutical classification on drugs	**BSCR601_CO3:** Explain & demonstrate the process of quality assurance in drug development process	**3**
Unit IV: Regulatory **authority** ICH-GCP, Indian GCP,	APPLY AND DISCUSS: ICH-GCP, Indian GCP, Schedule Y, Protocol designing & development emphasis to IB; DEFINE, REMEMBER, APPLY	**BSCR601_CO4:** Express the role of regulators and drug development process	**3**

Schedule Y, Protocol designing & development emphasis to IB; Ethical committee IEC and its composition, Clinical Study report, Key player's of clinical trial, International Scenario of Regulatory Aspects : FDA, CFR; Regulatory aspects of medical devices, biological & Electronic Submissions, Dossier filing. Basic concepts of Intellectual Property rights	AND DISCUSS Ethical committee IEC and its composition, DEFINE, DESCRIBE, APPLY AND DISCUSS Clinical Study report, Key player's of clinical trial, International Scenario of Regulatory Aspects : FDA, CFR; DEFINE, DISCUSS Regulatory aspects of medical devices, biological & Electronic Submissions, Dossier filing. Basic concepts of Intellectual Property rights		
Unit V: Drug Evaluation and Clinical Development Phases of developmental clinical trials, Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV, Placebo response, advantages and disadvantages of placebo	ANALYZE: Phases of developmental clinical trials, Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV, Placebo response, advantages and disadvantages of placebo	**BSCR601_CO5:** Scientifically differentiate the phase of clinical trial	**5**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR601_CO 1	3			3	2			1	2	-

BSCR601_CO 2	2	3	2			2	2	2	-	-
BSCR601_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR601_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR601_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

18. Mid-Term Exams
19. End-Term Exam
20. Portfolio Oral Presentation
21. Class Activity
22. Assignment

6. Teaching Tools

22. Blackboard Teaching
23. Power point slides
24. Practice assignments
25. LMS Moodle
26. Video lectures

7. Unit-Wise Weightage of marks

Unit	**CO**	**Marks**
1	BSCR601_CO1	20
2	BSCR601_CO2	20
3	BSCR601_CO3	20
4	BSCR601_CO4	20
5	BSCR601_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR601_CO1	1,2,3,4,7	1,4,5
2	BSCR601_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR601_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR601_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR601_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

23. Bibliography and References

Prescribed Texts:

- Principles and Practice of Clinical Research- John I. Gallin, Frederick P. Ognibene2007
- Designing Clinical Research- Stephen B. Hulley, Steven R. Cummings, Warren S. Browner · 2011
- Essentials of Clinical Research- Stephen P. Glasser · 2014

Reference Books:

- Drug Safety: From Molecule To Man- Park
- Drugs: From Discovery To Approval - NG
- Manual Of Clinical Microbiology- Murray
- Patient Care In Community Practice- Harman
- Introduction To Clinical Pharmacology- Edmunds

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials

- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 604	Major (Fundamental)	Clinical Pharmacology	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: General pharmacology Introduction to pharmacology, Definition, scope of pharmacology, sources of drugs, route of drug administration, competitive and non-competitive inhibition, Pharmacokinetics, Process, kinetics of inhibition, elimination, excretion	DEFINE, REPEAT, REMEMBER, DESCRIBE Introduction to pharmacology, Definition, scope of pharmacology, sources of drugs, route of drug administration, competitive and non-competitive inhibition, Pharmacokinetics, Process, kinetics of inhibition, elimination, excretion	**BSCR604_CO1 :** Describe role of Pharmacology with its applications	**1**
Unit II: Pharmacodynamics Principles and mechanism of action, Drug receptors, G-protein coupled receptors, ion channel receptors, transmembrane enzyme linked receptors, Therapeutic index, Adverse drug reaction, Pharmacovigilance	DEFINE, DESCRIBE, EXPLAIN, EXPERIMENT AND DISCUSS: Principles and mechanism of action, Drug receptors, G-protein coupled receptors, ion channel receptors, transmembrane enzyme linked receptors, Therapeutic index, Adverse drug reaction,	**BSCR604_CO2:** Demonstrate & explain the Pharmacodynamics of drug action	**2**

	Pharmacovigilance		
Unit III: Clinical Trial Drug discovery, clinical evaluation of new drugs, Clinical trial phases in details, Recent clinical trial passed drugs	DEFINE, DEMONSTRATE, DISCUSS Drug discovery process in preclinical and post clinical trials	**BSCR604_CO3:** Explain & demonstrate the process of clinical research	**3**
Unit IV: 4 Pharmacology of drugs Herbal Drugs and Experimental establishment of the drugs (Animal Model and Cell Line), Drugs acting on peripheral nervous system, Drugs acting on Central nervous system, Neuromuscular agents, Antiepileptics, Sedatives and Hypnotics, Antipsychotics, Antidepressants, Antianxiety, Drugs used in Parkinson's Disease, Alzheimer's disease, Drug Database	DEFINE, DESCRIBE, APPLY AND DISCUSS: Herbal Drugs and Experimental establishment of the drugs (Animal Model and Cell Line), DEMONSTRATE Drugs acting on peripheral nervous system, Drugs acting on Central nervous system, Neuromuscular agents, Antiepileptics, Sedatives and Hypnotics, Antipsychotics, Antidepressants, Antianxiety, Drugs used in Parkinson's Disease, Alzheimer's disease, Drug Database	**BSCR604_CO4:** Experiment & Demonstrate the Pharmacology of Herbal Drugs	**4**
Unit V: Pharmacogenomics Introduction, Drug lists based on pharmacogenomics, Socio-economic impact, Databases of Pharmacogenomics, Drugs availability, Pharmacogenomics in Cardiovascular system,	DEFINE, REMEMBER, DESCRIBE AND ANALYZE: Introduction, Drug lists based on pharmacogenomics, Socio-economic impact, Databases of Pharmacogenomics, Drugs availability,	**BSCR604_CO5:** Explain the role and application of Pharmacogenomics in drug development process	**4**

Diabetes, Cancer, Case studies on Pharmacogenomics	DEMONSTRATE Pharmacogenomics in Cardiovascular system, Diabetes, Cancer, Case studies on Pharmacogenomics		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR604_CO 1	3	1	2	2	2			1	2	-
BSCR604_CO 2	2	3	3		1	2	3	2	2	2
BSCR604_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR604_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR604_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping

1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	48	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

10. Mid-Term Exams
11. End-Term Exam
12. Class Activity
13. Portfolio Oral Presentation
14. Assignment

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments

11. LMS Moodle
12. Video lectures

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR604_CO1	20
2	BSCR604_CO2	20
3	BSCR604_CO3	20
4	BSCR604_CO4	20
5	BSCR604_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR604_CO1	1,2,3,4,7	1,4,5
2	BSCR604_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR604_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR604_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR604_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

15. Bibliography and References

Prescribed Texts:

- Basic and Clinical Pharmacology by Bertram G. Katzung
- The pharmacological basis of Therapeutics by Laurence L. Brunton (Godman and Gilman's)
- Modern Pharmacology with clinical applications by Charles R. Craig and Robert E. Stitzel
- Desk reference of Clinical Pharmacology by Manuchair Ebadi

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- The Pharmacogenomics
- Clinical Endocrinology

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 611	Major (Depth)	BIOETHICS	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: An introduction to patent law Introduction to patent law, World trade organization and intellectual property provisions, Legal protection in research and development. Medical Research related patenting and ethical consideration.	DEFINE, REMEMBER, DESCRIBE IP, Patent, WTO, Legal protection in research and development. Medical Research related patenting and ethical consideration.	**BSCR611_CO1 :** Understand and Define & explain the IP rights in Clinical Research	**1**
Unit II: Introduction to Bioethics: Bioethics Introduction, Importance of Bioethics, Definition of the term Ethics in Biology, Health Ethics and Professional Ethics, History of Bioethics. Ethical principles and its type**.**	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Bioethics Introduction, Importance of Bioethics, Definition of the term Ethics in Biology, Health Ethics and Professional Ethics, History of Bioethics. Ethical principles and its type	**BSCR611_CO2:** Describe & explain the importance of ethics in Clinical Research	**2**

Unit III: Ethical Theories: Forms of ethical theories: Deontology, Utilitarian rights and Virtue. Types of ethical thoughts: Kantian, Rawls and Ross ethics. Duty of fidelity, Duty of justice and Duty of preparation. Duty of gratitude and Duty of beneficence	DEFINE, DISCUSS AND ANALYZE Ethical theories: Deontology, Utilitarian rights and Virtue. Types of ethical thoughts: Kantian, Rawls and Ross ethics. Duty of fidelity, Duty of justice and Duty of preparation. Duty of gratitude and Duty of beneficence	**BSCR611_CO3:** Explain & Discuss the ethical theories applicable in clinical research	**3**
Unit IV: Healthcare Profession Healthcare profession: Healthcare provider, the client and healthcare provider-client relationship. Basic healthcare principles: Stewardship and totality.	DEFINE, DESCRIBE, APPLY AND DISCUSS Healthcare profession: Healthcare provider, the client and healthcare provider-client relationship. Basic healthcare principles: Stewardship and totality.	**BSCR611_CO4:** Understand the role of healthcare professional in maintaining the client relationship	**3**
Unit V: Biosafety Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)	DEFINE, REMEMBER, DESCRIBE, DISCUSS, APPLY: Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices	**BSCR611_CO5:** Explain the role and application of Bioethics & GMP in Clinical Research	**4**

	(GMP)		

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR611_CO 1	**3**	**1**	**2**	**3**	**2**	**-**	**-**	**1**	**2**	**-**
BSCR611_CO 2	**2**	**3**	**3**	**3**	**1**	**-**	**-**	**2**	**2**	**2**
BSCR611_CO 3	**2**	**2**	**2**	**3**	**1**	**1**	**2**	**2**	**2**	**-**
BSCR611_CO 4	**2**	**2**	**-**	**3**	**1**	**-**	**2**	**2**	**2**	**2**
BSCR611_CO 5	**1**	**-**	**-**	**3**	**-**	**-**	**1**	**2**	**-**	**2**

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	**24**	**24**	**72**	**02**	**12**	**10**

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

9. Mid-Term Exams
10. End-Term Exam
11. Class Activity
12. Portfolio Oral Presentation
13. Assignment

6. Teaching Tools

13. Blackboard Teaching
14. Power point slides
15. Practice assignments
16. LMS Moodle
17. Video lectures

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR611_CO1	20
2	BSCR611_CO2	20
3	BSCR611_CO3	20
4	BSCR611_CO4	20
5	BSCR611_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools

1	BSCR611_CO1	1,2,3,4,7	1,4,5
2	BSCR611_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR611_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR611_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR611_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

- Bioethics: An introduction for the Biosciences by Ben Mepham (Oxford).
- IPR, Biosafety and Bioethics by Deepa Goel and Shomni Parashar (Pearson pub.)

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 614	Major (Depth)	Regulatory Affairs	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
UNIT I Evolution of Regulatory controls: An international comparison, Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki, ICH, NICE	DEFINE, REMEMBER, DESCRIBE, Evolution of Regulatory controls: An international comparison, Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki, ICH, NICE	**BSCR614_CO1 :** Define & explain the regulatory controls in clinical research	**1**
UNIT II Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New	DEFINE, DESCRIBE, EXPLAIN AND DISCUSS Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New	**BSCR614_CO2:** Describe the process of drug regulatory process for new discovery	**2**

Drug Application (ANDA), Paper NDA, Market authorization holders (MAH), its procedures, Post-marketing Surveillance (PMS),	Drug Application (ANDA), Paper NDA, Market authorization holders (MAH), its procedures, Post-marketing Surveillance (PMS),		
UNIT III US FDA regulations, Regulation of medical devices, Regulation of vaccines, Safety Report filing, Regulation of prescription drugs and non prescription drugs, Regulatory system in Key countries: Japan, Australia, China and Brazil	DEFINE, EXPERIMENT, DISCUSS US FDA regulations, Regulation of medical devices, Regulation of vaccines, Safety Report filing, Regulation of prescription drugs and non prescription drugs, Regulatory system in Key countries: Japan, Australia, China and Brazil	**BSCR614_CO3:** Explain & define the US FDA regulations in clinical research	**3**
UNIT IV International Conference on Harmonization (ICH) GCP guidelines, Overviews of GLP, Basic regulation of BA/BE studies, Introduction to IPR, patent, copyright, industrial design, Introduction to EMEA, OECD, ANVISA,	DEFINE, DESCRIBE, EXPERIMENT, APPLY AND DISCUSS International Conference on Harmonization (ICH) GCP guidelines, Overviews of GLP, Basic regulation of BA/BE studies, Introduction to IPR, patent, copyright, industrial	**BSCR614_CO4:** Understand the international regulatory guidelines	**4**

TGA, Regulation of Traditional and Herbal Remedies	design, Introduction to EMEA, OECD, ANVISA, TGA, Regulation of Traditional and Herbal Remedies		
Unit V Introduction to New Drug & Clinical Trial Rules, 2019, Rule 97, regulatory periods, fee, committees, Role of DGCI, CDSCO, Post trial regulation	DEFINE, REMEMBER, DESCRIBE APPLY AND DISCUSS: **Unit V** Introduction to New Drug & Clinical Trial Rules, 2019, Rule 97, regulatory periods, fee, committees, Role of DGCI, CDSCO, Post trial regulation	**BSCR614_CO5:** Explain & Describe the Indian govt regulations for the clinical research	**3**

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR614_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR614_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR614_CO 3	2	2	2	3	1	1	2	2	2	-

BSCR614_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR614_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	48	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

9. Mid-Term Exams
10. End-Term Exam
11. Portfolio Oral Presentation
12. Class Activity

13. Assignment

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle
12. Video lectures

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR614_CO1	20
2	BSCR614_CO2	20
3	BSCR614_CO3	20
4	BSCR614_CO4	20
5	BSCR614_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR614_CO1	1,2,3,4,7	1,4,5

2	BSCR614_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR614_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR614_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR614_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Prescribed Texts:

6. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by US-FDA. 2nd Edition, published by Informa Healthcare. ISBN 1420073540
7. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, by Gary Walsh, John J. Tobin published by Wiley-VCH Verlag GmbH. ISBN 9783527318773
8. Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
9. Principles and Practice of Clinical researxch by John I, Gallin;Academic Press Inc;3rd Edition
10. Regulatory guidelines ICH, USFDA, Indian GCP, EMEA etc

ONLINE RESOURCE MATERIAL AND JOURNALS:

6. Journal of Intellectual Properties Rights
7. The WIPO Journal
8. European Patent Bulletin
9. www.wipo.int

10. www.ficciipcourse.in

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 619	Major (Depth)	CLINICAL CASE STUDY	3	1	3	2	3	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction to Biomedical Research Introduction to Biomedical Research: Definition and scope of biomedical research Historical milestones and contributions to medical advancements Ethical considerations in biomedical research Disease Genesis: Understanding the etiology and pathogenesis of diseases Genetic factors and their role in disease development Environmental and lifestyle factors influencing disease initiation Cellular and molecular mechanisms of disease	DEFINE, DESCRIBE AND REMEMBER, Introduction to Biomedical Research: Definition and scope of biomedical research Historical milestones and contributions to medical advancements Ethical considerations in biomedical research Disease Genesis: Understanding the etiology and pathogenesis of diseases Genetic factors and their role in disease development Environmental and lifestyle factors influencing disease initiation Cellular and molecular mechanisms of disease progression	**BSCR619_CO1**: Describe the of principles and hands on relevant techniques of biomedical research viz disease genesis, diagnostics & management.	**1**

progression			
Unit II: Technical Documentations: Research Protocol: Components and structure of a research protocol Writing clear and concise research objectives Study design and methodology description Ethical considerations and participant protection Informed Consent Process: Importance and ethical principles of informed consent Developing an informed consent form Ensuring readability and comprehension for participants Addressing potential risks and benefits in consent documentation	DEFINE, EXPERIMENT AND DEMONSTRATE Research Protocol: Components and structure of a research protocol Writing clear and concise research objectives Study design and methodology description Ethical considerations and participant protection Informed Consent Process: Importance and ethical principles of informed consent Developing an informed consent form Ensuring readability and comprehension for participants Addressing potential risks and benefits in consent documentation	**BSCR619_CO2**: Experiment and demonstrate the preparation of technical document(protocol, informed consent, clinical report form, clinical study report).	**4**
Unit III: Ethical Theories: Application of Wet/Dry Lab Methodologies and Field Activity) Wet Lab Methodologies: Laboratory safety and good laboratory practices (GLP) Basic lab techniques	DEFINE,EXPLAIN, DISCUSS AND APPLY Wet Lab Methodologies: Laboratory safety and good laboratory practices (GLP) Basic lab techniques (pipetting, centrifugation, etc.)	**BSCR611_CO3: AA**pply wet/dry lab methodologies and field activity	**3**

(pipetting, centrifugation, etc.) Cell culture and tissue handling Molecular biology techniques (DNA extraction, gel electrophoresis, etc.)	Cell culture and tissue handling Molecular biology techniques (DNA extraction, gel electrophoresis, etc.)		
Unit IV: Knowledge of Progress in a Chosen Disease/Disorder Area Literature Review: Strategies for conducting a comprehensive literature search Critical appraisal of research articles and studies Identifying gaps and controversies in the chosen area Current Trends and Advances: Review of recent research publications and breakthroughs Understanding the latest technologies and methodologies Emerging treatment modalities and therapeutic targets Case Studies: Analyzing case studies related to the chosen disease/disorder Discussing diagnostic challenges and treatment	LEARN AND UNDERSTAND Healthcare profession: Healthcare provider, the client and healthcare provider-client relationship. Basic healthcare principles: Stewardship and totality. Literature Review: Strategies for conducting a comprehensive literature search Critical appraisal of research articles and studies Identifying gaps and controversies in the chosen area Current Trends and Advances: Review of recent research publications and breakthroughs Understanding the latest technologies and methodologies Emerging treatment modalities and therapeutic targets Case Studies:	**BSCR611_CO4:** **BSCR619_CO4**: Learn and understand the in depth knowledge of the progress in the chosen area of particular disease/disorder	**2**

decisions Learning from successful and unsuccessful clinical outcomes	Analyzing case studies related to the chosen disease/disorder Discussing diagnostic challenges and treatment decisions Learning from successful and unsuccessful clinical outcomes		
Unit V: Biosafety Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)	APPLY AND DEMONSTRATE: Biosafety: Introduction to biosafety and the health hazards. Introduction to the basic concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)	**BSCR619_CO5**: Apply and Demonstrate the knowledge for data generation, integration & statistical analysis using SW and design and interpret clinical case study.	**4**

CO\PO, PSO	**PO 1**	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PSO 1**	**PSO 2**	**PSO 3**
BSCR619_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR619_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR619_CO 3	2	2	2	3	1	1	2	2	2	-
BSCR619_CO	2	2	-	3	1	1	2	2	2	2

4										
BSCR619_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

9. Home assignments
10. Mid-Term Exams
11. End-Term Exam
12. Portfolio Oral Presentation
13. Class Activity

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR619_CO1	20
2	BSCR619_CO2	20
3	BSCR619_CO3	20
4	BSCR619_CO4	20
5	BSCR619_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR619_CO1	1,2,3,4,7	1,4,5
2	BSCR619_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR619_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7

4	BSCR619_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR619_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

1. Book: "Case Studies in Clinical Medicine" Author: R. R. Baliga Publisher: Elsevier India
2. Book: "Clinical Case Studies for the Family Nurse Practitioner" Authors: Leslie Neal-Boylan Publisher: Wiley-Blackwell
3. Book: "Case Files Internal Medicine" Authors: Eugene C. Toy, John T. Patlan, Mark T. Warner Publisher: McGraw-Hill Education / Medical

Internet:

FDA.GOV

Reference Material (Journals, Handout)

1. Journal: "Journal of Clinical Case Reports" Publisher: OMICS International Website: https://www.omicsonline.org/clinical-case-reports.php
2. Journal: "Clinical Case Studies" Publisher: SAGE Publications Website: https://journals.sagepub.com/home/ccs
3. Journal: "Case Reports in Medicine" Publisher: Hindawi Website: https://www.hindawi.com/journals/crim/

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 623	Major (Fundamental)	Mathematical modeling of Disease Transmission	3	1	3	2	3	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: **Introduction to Disease Transmission Modeling**	DEFINE, REPEAT, REMEMBER, DESCRIBE Introduction to disease transmission and its impact on public health. The role of mathematical modeling in understanding disease spread. Overview of different types of disease transmission models. Basic terminology and concepts in disease transmission modeling. The importance of parameters like R0 (basic reproduction number) in disease modeling. Historical examples of disease transmission modeling and their implications. Course Outcome: Understand the basics of disease transmission modeling and its significance in public health and epidemiology.	**BSCR 623_CO1 :** Understand the importance of mathematical modeling in studying epidemic dynamics	**1**
Unit II: Introduction to Disease Transmission Modeling	DEFINE, DESCRIBE, EXPLAIN, EXPERIMENT AND DISCUSS: Introduction to compartmental models and their structure. The SIR (Susceptible-Infectious-Recovered) model: Equations and assumptions. The SEIR (Susceptible-Exposed-Infectious-Recovered) model: Equations and interpretation. Extended compartmental models: SIRS, SEIRS, and other variations. Analyzing equilibrium points and stability of compartmental models. Case studies applying SIR and SEIR models	**BSCR 623_CO2:** Explain the role of mathematical modeling in predicting and preparing for unnaturally-born epidemic outbreaks.	**2**

	to real-world infectious diseases. Course Outcome: Analyze and apply compartmental models to study disease spread.		
Unit III: Introduction to Disease Transmission Modeling	DISCUSS AND ANALYZE Introduction to stochastic models and their relevance in disease transmission. Overview of probability distributions used in stochastic disease modeling. Stochastic differential equations and their application in modeling infectious diseases. Monte Carlo simulation methods for stochastic disease transmission modeling. Analyzing the impact of stochasticity on disease outbreak patterns. Incorporating stochasticity in network-based disease transmission models. Course Outcome: Comprehend stochastic models and their role in capturing randomness in disease transmission processes.	**BSCR 623_CO3:** Analyze invasion and outbreak sizes under different conditions and model scenarios.	**3**
Unit IV: Introduction to Disease Transmission Modeling	APPLY AND EVALUATE: Introduction to social networks and their connection to disease spread. Basics of network theory: Nodes, edges, and network properties. Network-based disease models: SIR on networks, percolation models, etc. Identifying and characterizing super-spreaders in networks. Network interventions and their effectiveness in controlling disease outbreaks. Case studies of disease transmission within different types of networks. Course Outcome: Understand network-based models and their significance in studying disease transmission within complex social networks.	**BSCR 623_CO4:** Evaluate epidemiological properties and their implications for disease control strategies, including herd immunity and vaccination thresholds.	**4**
Unit V: Data-Driven Disease Transmission Modeling	DEFINE, EVALUATE AND CREATE: Introduction to data-driven approaches in	**BSCR 623_CO5:** Create Model disease transmission dynamics using network	**5**

	disease transmission modeling. Data sources for disease modeling: Epidemiological data, social media, mobility data, etc. Data preprocessing: Cleaning, transforming, and handling missing data. Feature selection and engineering for building predictive models. Statistical methods for disease data analysis and visualization. Machine learning algorithms (e.g., regression, decision trees, SVM) in disease modeling. Evaluating model performance and dealing with overfitting. Case studies applying data-driven models to predict disease spread and inform interventions. Course Outcome: Apply data-driven approaches, such as statistical and machine learning techniques, to model and predict disease transmission.	models and interpret their findings.	

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR 623_CO 1	3	1	2	2	2			1	2	-
BSCR 623_CO 2	2	3	3		1	2	3	2	2	2

BSCR 623_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR 623_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR 623_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio PPT	Assignments	Self-Study	Others
Hours	36	20	12	06	26	24	20

5. Continuous and Submittive Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

16. Home assignments
17. Mid-Term Exams

18. End-Term Exam
19. Program implementation and laboratory written reports
20. Portfolio Oral Presentation

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	**BSCR 623**_CO1	20
2	**BSCR 623**_CO2	20
3	**BSCR 623**_CO3	20
4	**BSCR 623**_CO4	20
5	**BSCR 623**_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools

1	**BSCR 623**_CO1	1,2,3,4,7	1,4,5
2	**BSCR 623**_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	**BSCR 623**_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	**BSCR 623**_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	**BSCR 623**_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Prescribed Texts:

- Anderson and May (1991) 'Infectious Diseases of Humans: Dynamics and Control' (OUP). Provides an introduction to both mathematical and biological aspects of the course. We shall follow the broad outline of this book.
- Diekmann and Heesterbeek (2001) 'Mathematical Epidemiology of Infectious Diseases : Model Building, Analysis and Interpretation' (Wiley). A more mathematically-oriented book.
- Diekmann, Heesterbeek and Britton (2012) ‘Mathematical Tools for Understanding Infectious Disease Dynamics’ (Princeton)
- Daley and Gani (2001) 'Epidemic Modelling: An Introduction' (CUP) Provides examples involving statistical theory and stochastic modeling.
-

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics
- PlosOne
- AI in Healthcare

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 651	Major (Elective)	Epidemiology	2	2	6	2	4	Nil

2. Syllabus Unit-Wise

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I Introduction to Epidemiology Introduction & Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation	DESCRIBE, REMEMBER, RELATE Application, Types of epidemiology, Etiology of disease: Stages, Mechanisms and Causes of Disease, Host, Agent, Environment, and Vector, Risk Factors and Preventable Causes, BEINGS Model, UNDERSTAND, RELATE, DESCRIBE Ecological issues in epidemiology: Solution of Public Health Problems, Vaccination and Patterns of Immunity, Effects of Sanitation, Vector Control and Land Use Patterns, Role of epidemiologists: Investigation	BSCR651_CO1 Describe the epidemiology, philosophy and applications	2

of Epidemics and New Diseases, Biologic Spectrum of Disease, Surveillance of Community Health Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease.	of Epidemics and New Diseases, Biologic Spectrum of Disease, Surveillance of Community Health Interventions Setting Disease Control Priorities, Improving Diagnosis, Treatment, and Prognosis of Clinical Disease		
Unit II Epidemiologic Data Analysis Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates Standardization of Death Rates, Rates for Maternal and Infant Health	IDENTIFY, ASSOCIATE, ANALYZE, EVALUATE, Frequency: Incidence, Prevalence, Point Prevalence and Period Prevalence, Illustration of Morbidity, Relationship between Incidence and Prevalence, Risk: Definition and Limitations, Rates: Definition, Relationship between Risk and Rate, Types of Rates: Incidence Rate, Prevalence Rate, Incidence Density, Crude Rates, Standardization of Death Rates, Rates for Maternal and Infant Health	BSCR651_CO2 Analyze, Interpret & explain the epidemiology relationship with statistics	3
Unit III Epidemiologic Surveillance and Epidemic Outbreak Investigation	CLASSIFY, PREDICT, SKETCH, ORDER, HYPOTHESIZE, PLAN	BSCR651_CO3 Hypothesize & Design the Disease Surveillance Model to identification of epidemic	3

Surveillance of Disease: Role of Surveillance, Creation of Surveillance System, Methods and Functions of Disease Surveillance, Establishment of Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures	Surveillance of Disease: Role of Surveillance, Creation of Surveillance System, Methods and Functions of Disease Surveillance, Establishment of Baseline Data, Evaluation of Time Trends, Identification and Documentation of Outbreaks, Evaluation of Public Health and Disease Interventions, Setting of Disease Control Priorities, Study of Changing Patterns of Disease, Investigation of Epidemics, Patterns of Spread and Mode of Transmission, Control Measures, Follow-up Surveillance to Evaluate Control Measures	outbreak	
Unit IV Research Designs and Issues in Epidemiology Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological Studies, Observational Designs, Cohort Studies,	DEFINE, DEMONSTRATE, APPLY, PREPARE, COMPARE, DEVELOP Functions of Research Design, Types of Research Design: Observational Designs, Qualitative Studies, Cross-Sectional Surveys, Cross-Sectional Ecological Studies, Longitudinal Ecological	BSCR651_CO4 Design the Epidemiology Study	5

Case-Control Studies, Nested Case-Control Studies, Randomized Controlled Clinical Trials, Randomized Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues	Studies, Observational Designs, Cohort Studies, Case-Control Studies, Nested Case-Control Studies, Randomized Controlled Clinical Trials, Randomized Controlled Field Trials, Cost-Effectiveness Analysis, Research Issues in Epidemiology, Risk of Data Dredging, Ethical Issues		
Unit V Assessment of Risk and Benefit in Epidemiologic Studies Definition Of Study Groups, Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit	**RECOGNIZE, CLASSIFY, CALCULATE, PRIORITIZE, ASSESS** Comparison Of Risks In Different Study Groups: Absolute Differences in Risk, Relative Differences in Risk, Relative Risk (Risk Ratio), Odds Ratio, Impact of Risk Factors: Attributable Risk Percent in the Exposed, Population Attributable Risk, Population Attributable Risk Percent, Uses of Risk Assessment Data: Application of Risk Data to Policy Analysis, Estimating Benefit of Interventions in Populations, Cost-Benefit	BSCR651_CO5 Assessment & Evaluation of risk in Epidemiological Studies	4

Analysis, Application of Risk Measures to Counselling of Patients	Analysis, Application of Risk Measures to Counselling of Patients		

3. **Mapping Course Outcomes with POs and PSOs**

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR651_CO 1	3	-	-	3	2	-	-	2	2	-
BSCR651_CO 2	3	3	2	1	2	2	3	2	3	3
BSCR651_CO 3	2	3	3	2	2	3	-	2	3	3
BSCR651_CO 4	3	3	2	2	3	2	2	2	3	3
BSCR651_CO 5	2	3	3	2	2	3	2	2	3	3

Key:

Level	Scale

--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio/Presentation	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

10. Mid-Term Exams
11. End-Term Exam
12. Portfolio Oral Presentation
13. Home assignments

6. Teaching Tools

8. Blackboard Teaching
9. Power point slides
10. Practice assignments
11. LMS Moodle

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	BSCR651_CO1	20
2	BSCR651_CO2	20
3	BSCR651_CO3	20
4	BSCR651_CO4	20
5	BSCR651_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR651_CO1	1,2,3,4,7	1,4,5
2	BSCR651_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR651_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR651_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR651_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

14. Bibliography and References

Text books

- High-Yield Biostatisitcs, Epidemiology and Public Health- AN Glaser
- Modern Epidemiology- Rothman, Greenland & Lash

- Biostatistics and Epidemiology: A Primer for Health and Biomedical Professionals- Smoller & Smoller
- Introduction to Epidemiology: Merrill

Internet

- WHO: Epidemiolgy http://www.who.int/topics/epidemiology/en/
- The BMJ http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/1-what-epidemiology
- CDC Epidemiology http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section1.html

Reference Material (Journals, Hand-outs)

Journals-

- Epidemiology- http://journals.lww.com/epidem/Pages/default.aspx
- Journal of Epidemiology & Community Health http://jech.bmj.com/

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Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 652	Major (Degree Elective)	Clinical Trial Management	3	2	3	4	4	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I: Introduction to Clinical Trials	DEFINE, REPEAT, REMEMBER, DESCRIBE Definition and objectives of clinical trials. Historical development of clinical trials and their impact on medical research. Importance of clinical trials in evidence-based medicine and healthcare decision-making. Overview of the different phases of clinical trials (Phase I to Phase IV) and their respective goals. Ethical considerations in clinical trials, including informed consent, risk-benefit assessment, and protection of human subjects. Introduction to Good Clinical Practice (GCP) guidelines and their role in ensuring trial integrity.	**BSCR 652_CO1 :** understand the fundamentals of clinical trials, their importance in medical research, and the ethical considerations involved.	**1**
Unit II: Designing Clinical Trials	DEFINE, DESCRIBE, EXPLAIN, EXPERIMENT AND DISCUSS: Components of a well-designed clinical trial: research question, study population, interventions, and outcome measures. Randomization and blinding in clinical trial design to minimize bias. Understanding the concept of control groups and their role in comparing treatment efficacy. Sample size calculation and power analysis to ensure adequate statistical power. Different types of clinical trial designs: parallel, crossover, factorial, and their applications. Introduction to adaptive clinical trial designs and their advantages.	**BSCR 652_CO2:** design and plan a clinical trial, considering various factors like sample size, randomization, and blinding.	**2**

Unit III: Data Collection and Management in Clinical Trials	DISCUSS AND ANALYZE Data collection methods in clinical trials: case report forms (CRFs), electronic data capture (EDC), and patient-reported outcomes (PROs). Importance of data quality and accuracy in clinical trial research. Standard Operating Procedures (SOPs) for data collection and ensuring consistency across study sites. Data monitoring and quality assurance during the trial period. Handling missing data and strategies for data imputation. Data management challenges in multicenter trials and strategies to address them. Course Outcome: Implement effective data collection and management strategies in clinical trials.	**BSCR 652_CO3:** Analyze data management challenges and solutions in large-scale multicenter trials.	**3**
Unit IV: Ethical and Regulatory Aspects of Clinical Trials	APPLY AND EVALUATE: DEMONSTRATE Key ethical principles in clinical research: autonomy, beneficence, non-maleficence, and justice. Role of institutional review boards (IRBs) in reviewing and approving clinical trial protocols. Overview of regulatory authorities and their role in overseeing clinical trials (e.g., FDA, EMA). Informed consent process: elements of informed consent and obtaining voluntary participant agreement. Assessment of risk and benefits in clinical trial design and participant safety. Reporting adverse events and serious adverse events (SAEs) during the trial.	**BSCR 652_CO4:** Analyze data management challenges and solutions in large-scale multicenter trials.	**4**
Unit V: Analysis and Interpretation of Clinical Trial Results	DEFINE, EVALUATE AND CREATE: Basic statistical concepts used in clinical trial	**BSCR 652_CO5:** Evaluate the strengths and limitations of a clinical trial based on its	**5**

	data analysis: p-values, confidence intervals, and hypothesis testing. Intention-to-treat (ITT) analysis and per-protocol analysis: differences and interpretation. Commonly used statistical tests in clinical trials: t-tests, chi-square tests, and analysis of variance (ANOVA). Interpreting clinical trial results in the context of primary and secondary endpoints. Publication bias and its impact on reporting clinical trial outcomes. Communicating trial results to stakeholders: scientific community, clinicians, and the general public. DEMONSTRATE Publication bias and its impact on reporting clinical trial outcomes. Communicating trial results to stakeholders: scientific community, clinicians, and the general public.	design and results.	

3. Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR 652_CO 1	3	1	2	2	2			1	2	-
BSCR 652_CO 2	2	3	3		1	2	3	2	2	2
BSCR 652_CO 3	2	2	2	2	1	-	-	2	2	-
BSCR 652_CO 4	2	2	2	2	1	-	-	2	2	2
BSCR 652_CO 5	1	-	-	1	-	-	-	2	-	-

Key:

Level	Scale
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio PPT	Assignments	Self-Study	Others
Hours	36	20	12	06	26	24	20

5. Continuous and Submittive Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

21. Home assignments
22. Mid-Term Exams
23. End-Term Exam

24. Program implementation and laboratory written reports
25. Portfolio Oral Presentation

7. Unit-Wise Weightage of marks

Unit	CO	Marks
1	**BSCR 652**_CO1	20
2	**BSCR 652**_CO2	20
3	**BSCR 652**_CO3	20
4	**BSCR 652**_CO4	20
5	**BSCR 652**_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	**BSCR 652**_CO1	1,2,3,4,7	1,4,5
2	**BSCR 652**_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	**BSCR 652**_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	**BSCR 652**_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	**BSCR 652**_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Prescribed Texts:

- "Clinical Trials: A Methodologic Perspective" by Steven Piantadosi
- "Fundamentals of Clinical Trials" by Lawrence M. Friedman, Curt D. Furberg, and David L. DeMets
- "Design and Analysis of Clinical Trials: Concepts and Methodologies" by Shein-Chung Chow, Jen-Pei Liu, and Hansheng Wang
- "Handbook of Clinical Trials" edited by Karl E. Peace
- "Principles and Practice of Clinical Trial Medicine" by Richard Chin and Bruce Y. Lee
- "Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines" by Tom Brody

Reference Material (Journals, Handout)

- The New England Journal of Medicine
- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- The Pharmacogenomics
- PlosOne
- AI in Healthcare

Course code	Category	Course title	Scheme				Credits	Pre-requisite as per NEP 2020
			L	T	P	O		
BSCR 655	Major (Elective)	POLICY DEVELOPMENT	2	2	6	2	4	Nil

Unit & Title	Course Topic and Contents	Corresponding Cos	BT Level
Unit I - Population and Health Definition, concept and scope of demography, sources and health data, population and composition.	UNDERSTAND, DESCRIBE AND EXPLAIN Overview of Artificial Intelligence (AI) in Healthcare, Definition of AI and its significance in the healthcare industry.	BSCR655_CO1: describe the principles and hands on relevant expertise of developing policy documents in clinical trial.	**2**
Unit 2: Health Policy and Planning Health Framework and Health Policy..	REMEMBER, UNDERSTAND, APPLY AND EXPERIMENT Health Framework and Health Policy.	BSCR655_CO2: Understand and Experiment of new policies.	**4**
Unit 3: Aging and Society Theory of Aging and Biology of Aging, Chronic status, Healthcare services for older.	UNDERSTAND AND APPLY AND ANALYZE Theory of Aging and Biology of Aging, Chronic status, Healthcare services for older.	BSCR655_CO3: Analyze Chronic Conditions in older adults.	**3**
Unit 4: Health System Management Healthcare systems in India, Challenges in Healthcare System, Human Resource, Health Management Information System.	UNDERSTAND AND ANALYZE Healthcare systems in India, Challenges in Healthcare System, Human Resource, Health Management Information System.	BSCR655_CO4: Analyze Healthcare systems in India, Challenges in Healthcare System, Human Resource, Health Management Information System.	**3**
Unit 5: Health Economics Health Economics, Health Economics, Cost-Effective, Cost-	REMEMBER, UNDERST AND ANALYZE Health Economics, Health Economics, Cost-Effective, Cost-Benefit, and Cost-Utility	BSCR655_CO5: Analyze Health Economics and Health Insurance in India.	**4**

Benefit, and Cost-Utility Analysis, Health Insurance in India: Private and Community-Based Schemes	Analysis, Health Insurance in India: Private and Community-Based Schemes .		

3.Mapping Course Outcomes with POs and PSOs

CO\PO, PSO	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PSO 1	PSO 2	PSO 3
BSCR655_CO 1	3	1	2	3	2	-	2	1	2	-
BSCR655_CO 2	2	3	3	3	-	-	2	2	2	2
BSCR655_CO 3	2	2	2	3	1	1	2	2	2	-

BSCR655_CO 4	2	2	-	3	1	1	2	2	2	2
BSCR655_CO 5	1	-	-	3	-	-	1	2	-	2

Key:

Level	**Scale**
--	No Mapping
1	Low
2	Moderate
3	High

4. Course Delivery Plan

	Lectures	Tutorials	Practical	Portfolio	Assignments	Self-Study
Hours	24	24	72	02	12	10

5. Continuous Assessment

The outcome-based course assessment and evaluation tools are a combination of the following:

1. Home assignments
2. Mid-Term Exams

3. End-Term Exam
4. Class Attendance
5. Program implementation and laboratory written reports
6. Portfolio Oral Presentation
7. Quizzes
8. Practical Exam cum Viva

6. Teaching Tools

1. Blackboard Teaching
2. Power point slides
3. Practice assignments
4. LMS Moodle
5. Video lectures
6. Demonstrations
7. Virtual Labs

7. CO-Wise Weightage of marks

Unit	CO	Marks
1	BSCR655_CO1	20
2	BSCR655_CO2	20
3	BSCR655_CO3	20
4	BSCR655_CO4	20
5	BSCR655_CO5	20

8. Mapping of Teaching and Assessment Tools with Course Outcomes

S.No.	Course Outcomes	Assessment Tools	Teaching Tools
1	BSCR655_CO1	1,2,3,4,7	1,4,5
2	BSCR655_CO2	1.2,3,4,5,6,8	1,3,4,5,6,7
3	BSCR655_CO3	1,2,3,4,5,6,8	1,2,3,4,5,6,7
4	BSCR655_CO4	1,2,3,4,5,6,8	1,2,3,4,5,6,7
5	BSCR655_CO5	1,2,3,4,5,7,8	1,2,3,4,5,6,7

Bibliography and References

Text books:

Relevant material related to case study

Internet:

Relevant journals related to case study

3. Reference Material (Journals, Handout)

- NCBI
- CTRI
- USFDA

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