மனோன்மணியம் சுந்தரனார் பல்கலைக்கழகம்

MANONMANIAM SUNDARANAR UNIVERSITY

SYLLABUS FOR DIPLOMA IN CLINICAL RESEARCH PROGRAM OFFERED THROUGH DIRECTORATE OF VOCATIONAL EDUCATION (COMMUNITY COLLEGES AND VOCATIONAL SKILL DEVELOPMENT CENTRES) FROM 2019 – 2020

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கல்விசார் நிலைக்குழுக் கூட்டம்

MEETING OF THE STANDING COMMITTEE ON ACADEMIC AFFAIRS HELD ON WEDNESDAY THE 22nd JANUARY 2020

Program Code: 5210

DIPLOMA IN CLINICAL RESEARCH
மருத்துவம்சார் ஆராய்ச்சியில் பட்டயம்

SCHEME OF EXAMINATION

Subject code	Title of the Paper	Credit	Hours	Passing Minimum
Semester I				
C19CR11/E19CR01	Principles of drug design, development and Clinical Research	6	90	40/100
C19CR12/E19CR02	Clinical Trial Process	6	90	40/100
C19CR13/E19CR03	Basics of Biostatics & Clinical Data Management	6	90	40/100
C19CE10/E19CE10	Communicative English	6	90	40/100
C19CRP1/E19CRP1	Practical I – Laboratory testing Procedures - Basic pharmacology	4	120	40/100
Semester II				
C19CR21/E19CR04	Pharmacovigilance and Safety Reporting in Clinical Research	6	90	40/100
C19CR22/E19CR05	Regulatory Affairs in clinical Research	6	90	40/100
C19LS23/E19LS05	Life skill	6	90	40/100
C19CRP2/E19CRP2	Practical II-Laboratory Testing Procedure-Toxicological Labelling	4	120	40/100
C19CRPW/E19CRPW	Internship/Project	10	150	40/100

Eligibility for admission: Pass in 12thstd examination conducted by the Govt. of Tamil Nadu Board of Secondary Education, Government of Tamil Nadu or any other equivalent examination.

Examination: Passing Minimum for each paper is 40%. Classification will be done on the basis of percentage marks of the total marks obtained in all the papers and as given below:

40 % but less than 50 % - Third class
50 % but less than 60 % - Second class
60 % and above - First class

Theory Paper
Internal Marks-25
External Marks-75

Syllabus

First Semester:-

Paper I - Principles of drug design, development and Clinical Research
Paper II - Clinical Trial Process
Paper III - Basics of Biostatics & Clinical Data Management
Paper IV - Communicative English
Paper V - Practical I – Laboratory testing Procedures - Basic pharmacology

Second Semester:-

Paper VI - Pharmacovigilance and Safety Reporting in Clinical Research
Paper VII - Regulatory Affairs in clinical Research
Paper VIII - Life Skill
Paper IX - Practical II-Laboratory Testing Procedure-Toxicological Labelling
Paper X - Internship

***(Semester Pattern for Community College Only)**

Semester I

Course I

(C19CR11/E19CR01)Principles of drug design, development and Clinical Research

Unit – I: 18 Hrs

Drug Discovery process and Drug designing: Overview of Drug discovery process, purpose, main steps involved in new drug discovery process, timelines of each steps, advantages and purposes of each steps, ethics in clinical research, unethical trials, thalidomide tragedy, Phase-I, II, III, IV trials. Cost of Drug development, Protein Structure Prediction, Molecular Docking Studies and computer aided drug design.

Unit – II: 18 Hrs

Preclinical studies: Preclinical drug development, Guidelines for animal studies , Types of Pre-clinical trials, Pharmacokinetics: Overview, Routes of Drug Administration, Absorption (Bioavailability, Active and Passive Diffusion), Distribution (Modes of Distribution), Metabolism (First Pass Effect, Second Pass Effect, Half Life of Drugs, Biotransformation, Importance of CYP families in Metabolism), Excretion (Clearance Rate, Modes of Excretion) and Pharmacodynamics (PD): Receptor Activation, Commonly Targeted Receptors, Signaling Mechanism and Drug Action, Dose Response Curve, Action of Agonist and Antagonist, Efficacy and Toxicity (LD 50, ED 50).

Unit III: 18 Hrs

Clinical Development Definitions & Terminologies, History in Clinical Research, Regulations and Ethics in Clinical Research.IND, NDA& ANDA processes, requirements & guidelines. Clinical trial Preparation, Clinical Research Monitoring, Patient recruitment and retention.

Unit – IV: 18 Hrs

Clinical research: Scope of Clinical Research, Good Clinical Practices (GCP), History of clinical research, Nuremberg code, Belmonte report, Thalidomide disaster, Types of clinical trials, clinical trials Phases, Special Clinical Trials, Medical Devices Trials, Un-anticipated risk in clinical research.

Unit V 18 Hrs

Investigator Brochure, Informed Consent Form, Sponsor Monitor and Investigator responsibility, SOP in Clinical Trials, Clinical Trial Monitoring, Role of CRA, QA and QC in Clinical Trials, CRF Design. High-throughput screening in pharmacological drug discovery.

Reference:

1. A.R.Leach, Molecular Modelling Principles and Application, Longman, 1996.
2. J.M.Haile, Molecular Dynamics Simulation Elementary Methods, John Wiley and Sons,1997.
3. Satya Prakash Gupta, QSAR and Molecular Modeling, Springer - Anamaya Publishers,2008
4. Laurence Brunton, Bruce A Chabner, BjornKnollman (12th Edition): Pharmacological Basis of Therapeutics.

Course II

(C19CR12/E19CR02)Clinical Trial Process

Unit I **18 Hrs**

Types of clinical trials. Interventional and Observational.

Unit II **18 Hrs**

Design and organization of phase-I, phase-II, phase-III, phase-IV trials.

Unit III **18 Hrs**

Various regulatory requirements in clinical trials, Schedule Y, ICMR guidelines etc. Documents in clinical study Investigator Brochure (IB), Protocol & Amendment in Protocol,

Unit IV **18 Hrs**

Case Report Form (CRF), Informed Consent Form (ICF), Content of Clinical Trial Report Essential Documents in Clinical Trial Good Clinical Practice: ICH guidelines Indian GCP guidelines (CDCSO guidelines) ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y.

Unit V: **18 Hrs**

Study of various clinical trials (completed or ongoing) Clinical Trial Application in India Import & Export of Drug in India Investigational New Drug application (IND) Abbreviated New Drug Application (ANDA) New Drug Application (NDA).

REFERENCE BOOKS

1. A manager's guide to the design and conduct of clinical trials by Phillip I. Good
2. Clinical Trials: Design, Conduct and Analysis by Curtis L. Meinert
3. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting By Duolao Wang, Ameet Bakhai
4. Fundamentals of Clinical Trials by Lawrence M. Friedman, Curt D. Furberg, David DeMets
5. Management of data in clinical trials by Eleanor McFadden
6. Principle and Practice of Clinical Research by John I. Gallin, Frederick P Ognibene
7. Clinical Data Management By Richard K. Rondel, Sheila A. Varley, Colin F. Webb
8. Principles and Practice of Clinical Research by John a Gallin
9. Understanding Oracle Clinical by Safari Books online

Course III

(C19CR13/E19CR03) Basics of Biostatics & Clinical Data Management

Unit I **18 Hrs**

Fundamentals of Biostatistics: Data classification, data distribution, descriptive methods for categorical data, descriptive methods for continuous data. Statistical, estimation of parameters, comparison of population, proportions, comparison of population means, correlation and regression.

Unit II **18 Hrs**

Other Issues in Data Analysis Poor quality or missing data, Intention to-treat analysis, Competing events, Covariate adjustment. subgroup analyses, comparison of multiple variables, use of cut points, meta-analysis of multiple studies. Probability and Normal Distributions, Estimation, Hypothesis Testing, ANOVA (One way and two way).

Unit III **18 Hrs**

Statistics for clinical trials: Types of data in clinical trials, Computer System Validation: 21 CFR 11, CTM system, Systems Software Validation Issues: auto encoder, User Acceptance Test, SDLC; Oracle Clinical, workflow, Intelligent Character Recognition; Basic Clinical Research tools and Resources for Data Management and Analysis SAS CLINICAL: Introduction to SAS in CDM, components of SAS, Different data types, Base/SAS, SAS/STAT, SAS/GRAPH, SAS/ACCESS, SAS Procedures, SAS Macros, Brief Introduction to SQL, SAS/SQL, SAS Enterprise Guide 4.1, SPSS, Graphpad Prism

Unit IV **18 Hrs**

Case Study using SAS: TLG (Tables listings and Graphs) of clinical trials in SAS, Tables in clinical trials, Screening failures, Subject disposition, Subject disposition by visits, Premature discontinuation from study medication, Subject disposition by center, Protocol deviation, Demographics and baseline characteristics, Medical and surgical history, Gynecological history, Screening Pap smear, mammography and serum pregnancy test results.

Unit V **18 Hrs**

NGS data analysis: Downloading the genome sequence, Quality Check & Filtering, Read assembly, Gene prediction, Gene annotation, Advance annotation and analysis, Diseases variant identification, Haplogroup identification, Binding site identification, pathway analysis.

REFERENCE BOOKS

1. Analysis of Clinical Trials Using SAS: A Practical Guide by Alex Dmitrienko, Geert Molenberghs, Christy Chuang-Stein, Walter W. Offen
2. Fundamentals of clinical trials by Lawrence M. Friedman, Curt Furberg, David L. DeMets
3. Medical Statistics: A Textbook for the Health Sciences by Michael J. Campbell, David Machin, Stephen J. Walters
4. Professional SAS Programmer's Pocket Reference by Rick Aster
5. Practical Guide to Clinical Data Management, Second Edition by Susanne Prokscha
6. support.sas.com/documentation/online/91pdf

Course IV

(C19CE10/E19CE10) COMMUNICATIVE ENGLISH

1. **Basic Grammar**:
   a. Review of grammar
   b. Remedial study of grammar
   c. Simple sentence
   d. Word passive voice etc.

2. **Bubbling Vocabulary**:
   a. Synonyms
   b. Antonyms
   c. One – work Institution

3. **Reading and Understanding English**
   a. Comprehension passage
   b. Précis – writing
   c. Developing a story from hints.

4. **Writing English**
   a. Writing Business letters.
   b. Paragraph writing
   c. Essay writing
   d. Dialogue writing

5. **Speaking English**
   a. Expressions used under different circumstances
   b. Phonetics

Reference : 1. V.H.Baskaran – "English Made Easy"

2. V.H.Baskaran – "English Composition Made Easy"

(Shakespeare Institute of English Studies, Chennai)

3. N.Krishnaswamy – "Teaching English Grammar"

(T.R.Publication, Chennai)

4. "Life Skill" – P.Ravi, S.Prabakar and T.Tamzil Chelvam,

M.S.University, Tirunelveli.

Course V

(C19CRP1/E19CRP1)Practical I

Laboratory testing Procedures -Basic pharmacology

1. Routes of administration.
2. To demonstrate the effects of sympathomimetic and sympatholytic drugs on frog's heart.
3. To study the effects of adrenaline on rabbit's eyes.
4. To study the effects of local anesthetic drug.

Semester II

Course VI

(C19CR21/E19CR04) Pharmacovigilance and Safety Reporting in Clinical Research

Unit I: 18 Hrs

Introduction: Overview of pharmacovigilance. Standard Terms and Terminology in Pharmacovigilance.

Unit II: 18 Hrs

Medical Evaluation of Adverse Events in Pharmacovigilance, Adverse Events Reporting System and form, Diagnosis and managements of ADRs, Medical Evaluation of AE

Unit III: 18 Hrs

Case Processing: Global Perspective of Pharmacovigilance, Single case processing, Case narrative writing.

Unit IV: 18 Hrs

Pharmacovigilance reporting database, Signal detection, Management and Risk Assessments & Evaluation, Quality system in PV, Expedited Reporting Criteria, PSUR & PBRER. PV Database and signal detection, Risk Assessments & Managements.

Unit V: 18 Hrs

Medical dictionary for regulatory Activities medDRO, PV laws and guidelines, SOPS in PV, PV auditing and inspection, Regulatory aspects in PV.

Reference:

1.Colbert's Manual of Drug Safety and pharmacovigilance By Barton L Colbert.

2. Principles and Practice of Clinical Research by John A Gallin

Course VII

(C19CR22/E19CR05) Regulatory Affairs in clinical Research

Unit I: **18 Hrs**

Historical Perspective, Ethical Issues, ICH-GCP Guidelines I and II, Schedule Y, ICMR guidelines for biomedical research, Regulatory Issues in US, Australia, Japan and Europe (UK), Regulatory Issues in India

Unit II: **18 Hrs**

General principles of medicine regulation (both pre- and post- approval). Impact of medical legislative requirement on regulatory activities within the pharmaceutical company.

Unit III: **18 Hrs**

Regulatory bodies in India. Role of national and international agency in medicine regulation. Medical device registration in India.

Unit IV **18 Hrs**

Drug price control order in force. IPR Laws on trademark and copyrights.

Unit IV: **18 Hrs**

Regulatory consideration for preclinical and clinical testing. Regulation and Registration of medical devices. Regulation of biosimilar in India and Europe. Worldwide regulation of herbal product.

REFERENCE BOOKS

1. A manager's guide to the design and conduct of clinical trials by Phillip I. Good

2. Clinical Trials: Design, Conduct and Analysis by Curtis L. Meinert

3. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting By Duolao Wang, Ameet Bakhai

4. Fundamentals of Clinical Trials By Lawrence M. Friedman, Curt D. Furberg, David DeMets

5. Management of data in clinical trials by Eleanor McFadde.

Course VIII

(C19LS23/E19LS05) LIFE SKILL

I Life Coping or adjustment

(a) External and internal influence in one's life
(b) Process of coping or adjustment
(c) Coping with physical change and sexuality
(d) Coping with stress, shyness, fear, anger far live and criticism.

II Attitude

(a) Attitude
(b) Self acceptance, self – esteem and self actualization
(c) Positive thinking

III Problem Solving

(a) Goal Setting
(b) Decision Making
(c) Time Management and stress Management.

IV Computers

(a) Introduction to Computers
(b) M.S.Office
(c) Power Point

V Internet

(a) Introduction to internet
(b) E – mail
(c) Browsing

References:

1) Life Skill Programme course I & II by Dr. Xavier Alphona MCRDCE Publications. R.K.Mutt Road, Chennai – 28
2) ஆளுமை பண்பு வளர்த்தல் மற்றும் தகவல் தொடர்பு by M.Selvaraj Community College,Palayamkottai
3) "Life Skill" –P.Ravi, S.Prabahar & T.Tamil Chelvam, M.S. University, Tirunelveli

Course IX

(C19CRP2/E19CRP2)Laboratory Testing Procedure-Toxicological Labelling

1. Preparation of standard solutions (Ringer solution, ii. Tyrode solution, iii. Kerb solution, iv. Normal saline solution).
2. Effect of hypnotics in mice.
3. Test for pyrogens.
4. Taming and hypnosis potentiating effect of chlorpromazine in mice/rats.

Course X

(C19CRPW/E19CRPW) Internship
