SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

Department of Biotechnology	LP: BT18025 Rev. No: 01 Date: 04/07/2023
~~B.E~~/B.Tech/~~M.E/M.Tech~~ : **Biotechnology** Regulation: 2018 PG Specialisation : NA Sub. Code / Sub. Name : BT18025/Lifestyle Diseases And Clinical Trials Unit : I	

UNIT –I **INTRODUCTION** **8**

Overview of NCDs, Lifestyle Disorders, Epidemiology, CVD, Diabetes, Stroke, COPD, Mental Health, Stress, Role of diet & nutrition.

OBJECTIVE:
The aim of the course is to give strong foundation and advanced information on management of life-style disorders.

Session No *	Topics to be covered	Ref	Teaching Aids
1.	Overview and impact of Non-Communicable Diseases over the period.	T1:1157-1158	LCD
2.	Effect of Lifestyle Disorders on human health and Epidemiology.	T1:861-867	LCD
3.	Effect of cardiovascular diseases (CVD), symptoms, diagnosis, and treatment	T1: 3-11, 478-479	LCD
4.	Diagnosis and different types of Diabetes, Mechanisms of action of hormones, proteins, and genes on the onset of diabetes.	T1:383-389	LCD
5.	Occurrence of Stroke irrespective of age & gender and its prevention and treatment.	T1:40	LCD
6.	Diagnosis, prevention, and treatment of Chronic obstructive pulmonary disease (COPD).	T1:612-613	LCD
7.	Importance of diet & nutrition in Stress Management to overcome Lifestyle Disorders.	T1:1007-1012	LCD
8.	Importance of diet & nutrition in Stress Management to overcome Lifestyle Disorders.	T1:1007-1012	LCD
Content beyond syllabus covered (if any): Other lifestyle-oriented disorders apart from syllabus.			

* Session duration: 50 minutes

Sub. Code / Sub. Name : BT18025/Lifestyle Diseases And Clinical Trials
Unit : II

UNIT- II ROLE OF CLINICAL TRIALS IN NEW DRUG DEVELOPMENT 8

Introduction to clinical trials, Clinical trial phases, Clinical study designs, Phase 0 studies, Phase I and subtype studies, Phase II studies, Phase III studies, Phase IV studies, Clinical Investigation and Evaluation of Medical Devices & IVDs, Key concepts of Clinical Investigation.

OBJECTIVE:
This course provides core responsibilities for the development and monitoring of the drug and the preparation of medicines according to the norms.

Session No *	Topics to be covered	Ref	Teaching Aids
9.	Introduction to clinical trials and different of clinical trial.	T2:1-3 T3: 1-4	LCD
10.	Clinical study designs- observational and experimental design for optimization of clinical trial conduct.	T2:1-3 T3:4-6	LCD
11.	The design and application of Phase 0 studies, Phase I, and subtype clinical studies.	T2:4 T3:14-26	LCD
12.	The design and application of Phase II studies.	T2:5	LCD
13.	The design and application of Phase III studies and Phase IV studies.	T2:7-10	LCD
14.	Clinical Investigation and Evaluation of Medical devices & In vitro diagnostics (IVD).	T2:49-62	LCD
15.	Clinical Investigation and Evaluation of Medical devices & In vitro diagnostics (IVD).	T2:49-62	LCD
16.	Key concepts and of Clinical Investigation	T2:49-62	LCD
Content beyond syllabus covered (if any): Exploring the clinical investigation through case studies.			

* Session duration: 50 mins

Sub. Code / Sub. Name : BT18025/Lifestyle Diseases And Clinical Trials
Unit : III

UNIT -III REGULATORY ASPECTS RELATED TO CLINICAL TRIALS 9

ICH GCP, Quality assurance in Clinical research, The ethics of randomized clinical trials, The role of placebo in clinical trials, Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data, Data safety monitoring boards, Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research.

OBJECTIVE:
To describe the principles involved in ethical, legal and regulatory issues in clinical trials.

Session No *	Topics to be covered	Ref	Teaching Aids
17.	International Conference on harmonisation and guidelines on good clinical practices.	R1-24 & R2:419-420 &583-585	LCD
18.	Quality assurance and its implications in clinical research.	R1:443	LCD
19.	The ethics of randomized and its application in various phases of clinical trials.	T4:427-439	LCD
20.	The role of placebo in various phases of clinical trials.	R2:136-141	LCD
21.	Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data.	R2: 441, 541, 594	LCD
22.	Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data.	R2: 441, 541, 594	LCD
23.	Data safety monitoring boards and responsibilities of sponsor.	R2:464-465	LCD
24.	Contract research organization and investigator in ethical conduct of clinical research.	R2:445-447	LCD
25.	Contract research organization and investigator in ethical conduct of clinical research.	R2:445-447	LCD
Content beyond syllabus covered (if any): Role of CRO in different phases of clinical trial.			

* Session duration: 50 mins

Sub. Code / Sub. Name : BT18025/Lifestyle Diseases And Clinical Trials
Unit : IV

UNIT -IV BASICS OF STATISTICAL ANALYSIS 12

Definition, Application, Sample size, Importance of sample size, Factors influencing sample size, Dropouts, Statistical tests of significance, Type of significance tests, Parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), Non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), Null hypothesis, P values, Degree of freedom, Interpretation of P values.

OBJECTIVE:

To gain knowledge in in the basic bio-statistical techniques involved in clinical research.

Session No *	Topics to be covered	Ref	Teaching Aids
26.	Definition, Application importance of sample size and factors influencing sample size and dropouts.	R1:80-87, 167-184	LCD
27.	Definition, Application importance of sample size and factors influencing sample size and dropouts.	R1:80-87,167-184	LCD
28.	Statistical tests of significance and types.	R1:185-196	LCD
29.	Statistical tests of significance and types.	R1:185-196	LCD
30.	Parametric tests (students "t" test, ANOVA, Correlation coefficient, regression)	R1:197-217	LCD
31.	Parametric tests (students "t" test, ANOVA, Correlation coefficient, regression)	R1:197-217	LCD
32.	Parametric tests (students "t" test, ANOVA, Correlation coefficient, regression)	R1:197-217	LCD
33.	Non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test)	R1:197-217	LCD
34.	Non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test)	R1:197-217	LCD
35.	Non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test)	R1:197-217	LCD
36.	Null hypothesis, P values, Degree of freedom	R1:217-235	LCD
37.	Interpretation of P values.	R1:217-235	LCD
Content beyond syllabus covered (if any): Research problems involving the statistical analysis.			

* Session duration: 50 mins

Sub. Code / Sub. Name : BT18025/Lifestyle Diseases And Clinical Trials
Unit : V

UNIT- V REPORTING OF TRIALS 8

Overview of reporting, Trial profile, Presenting baseline data, Use of tables, Figures, Critical appraisal of report, Meta-analysis.

OBJECTIVE:

To gain knowledge in in the basic bio-statistical techniques involved in clinical research.

Session No *	Topics to be covered	Ref	Teaching Aids
38.	Overview of reporting- Interpretation clinical trials.	R1:365-376	LCD
39.	Trial profile- Reporting randomized control trials.	R1:377-384	LCD
40.	Presenting baseline data determining demographic characteristics, disease-related risk.	R1:385-391	LCD
41.	Types of tables used in clinical trial reports, providing standard.	R1:391-406	LCD
42.	The various types of graphical representations that would be appropriate for different kinds of data.	R1:407-427	LCD
43.	Critical appraisal of report- the ability to quickly and effectively evaluate the results of a clinical trial.	R1:427-438	LCD
44.	Critical appraisal of report- the ability to evaluate the results of a clinical trial.	R1:427-438	LCD
45.	Meta-analysis- systematic method for combining the results	R1:439-446	LCD
Content beyond syllabus covered (if any): Role of Meta-analysis in different phases of clinical trial.			

* Session duration: 50 mins

TEXT BOOKS:

1. Rippe J, "Lifestyle medicine", 2nd Edition, CRC press, Newyork, 2013.

2. Lawrence M. Friedman, "Fundamentals of Clinical Trials", Springer Science & Business Media, 2010.

3. Stuart J. Pocock, "Clinical Trials: A Practical Approach", John Wiley & Sons, 2013.

4. David Machin, Simon Day, Sylvan Green, "Textbook of Clinical Trials", John Wiley & Sons, 2007.

REFERENCES:

1. Duolao Wang and AmeetBakhai, "Clinical trials, A practical guide to design, analysis and reporting", Remedica. 2006.

2. Tom Brody, "Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines", Academic Press, 2016.

	Prepared by	Approved by
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Designation	Assistant Professor, Biotechnology	HOD
Date	04/07/2023	04/07/2023
Remarks*: This lesson plan will be followed in the subsequent years		
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* If the same lab plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD

4/7/23