



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

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 (wilcoxon 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 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 (wilcoxon rank tests, analysis of variance, correlation, chi square test)	R1:197-217	LCD
34.	Non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test)	R1:197-217	LCD
35.	Non-parametric tests (wilcoxon 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 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



SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

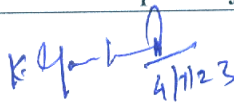
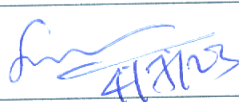
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TEXT BOOKS:

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