



SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

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Department of Biotechnology		LP: BT22075
B.E/B.Tech/M.E/M.Tech: Biotechnology		Rev. No: 00
Regulation: 2022		Date: 12/06/2026
PG Specialisation : NA		
Sub. Code / Sub. Name: BT22075/Clinical Trials and Healthcare Policies in Biotechnology		

Unit :I Role of Clinical Trials in New Drug Development**(9 Hrs)**

Unit Syllabus: 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: To acquire the knowledge on various phases of clinical trials.

Session No *	Topics to be covered	Ref	Teaching Aids
1.	Introduction to clinical trials	TB-1: Pg.No. 200–215	BB & PPT
2.	Clinical trial phases	TB-1: Pg.No.180–200	BB & PPT
3.	Clinical study designs	TB-1: Pg.No.180–200	BB & PPT
4.	Phase 0 studies,	TB-2: Pg.No.205–210	BB & PPT
5.	Phase I and subtype studies	TB-2: Pg.No.210–220	BB & PPT
6.	Phase II studies	TB-2: Pg.No.220–230	BB & PPT
7.	Phase III studies, Phase IV studies	TB-2: Pg.No.230–245 TB-2: Pg.No.245–255	BB & PPT
8.	Clinical Investigation and Evaluation of Medical Devices & IVDs	TB-2: Pg.No.350–370	BB & PPT
9.	Key concepts of Clinical Investigation.	RB 5: pg.no. 220–250	BB & PPT
Content beyond syllabus covered (if any):			

* Session duration: 50 minutes

**Sub. Code / Sub. Name: BT22075/Clinical Trials and Healthcare Policies in Biotechnology****Unit: II****Unit Syllabus: Regulatory Aspects Related to Clinical Trials****12 Hrs**

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 the sponsor, CRO, and investigator in the ethical conduct of clinical research

Objective: To inculcate the importance of regulations in clinical trials.

Session No *	Topics to be covered	Ref	Teaching Aids
10.	ICH GCP	TB-3: Pg.No. 150–170 RB 5: Pg.No. 20–45	BB & PPT
11.	Quality assurance in Clinical research	TB-3: Pg.No. 150–170	BB & PPT
12.	The ethics of randomized clinical trials	TB-3: Pg.No. 170–190 RB 5: Pg.No. 45–70	BB & PPT
13.	The role of placebo in clinical trials	TB-3: Pg.No. 190–205 RB 5: Pg.No. 70–90	BB & PPT
14.	Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data	TB-3: Pg.No. 205–230 RB 5: Pg.No. 90–120	BB & PPT
15.	Data safety monitoring boards	TB-3: Pg.No. 230–250 RB 5: Pg.No. 120–145	BB & PPT
16.	Responsibilities of the sponsor	TB-3: Pg.No. 250–275 TB-4: Pg.No. 410–440	BB & PPT
17.	CRO in the ethical conduct of clinical research	TB-3: Pg.No. 250–275 TB-4: Pg.No. 410–440	BB & PPT
18.	Investigator in the ethical conduct of clinical research	TB-3: Pg.No. 250–275 TB-4: Pg.No. 410–440	BB & PPT
Content beyond syllabus covered (if any):			

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Sub. Code / Sub. Name: BT22075/ Clinical Trials and Healthcare Policies in Biotechnology**Unit: III****Unit Syllabus: Reporting of Trials****9 Hrs**

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

Objective: To impart the knowledge on preparation of report based on clinical trials.

Session No *	Topics to be covered	Ref	Teaching Aids
19.	Overview of reporting	TB-2: pg.no. 520–540 RB 2: pg.no. 250–270	BB & PPT
20.	Trial profile	TB-2: pg.no. 540–550 RB 2: pg.no. 270–285	BB & PPT
21.	Presenting baseline data	TB-2: pg.no. 550–565 TB-3: pg.no.. 295–310	BB & PPT
22.	Use of Tables	TB-2: pg.no. 565–585 TB-3: pg.no. 310–330	Experiential learning
23.	Figures	TB-2: pg.no. 565–585 TB-3: pg.no. 310–330	Experiential learning
24.	Critical appraisal of the report	TB-2: pg.no. 585–605 TB-3: pg.no. 330–350	BB & PPT
25.	Meta-analysis.	TB-2: pg.no 605–630 TB-3: pg.no.. 350–370	BB & PPT
26.	Case study		Experiential learning
27.	Case study		Experiential learning
Content beyond syllabus covered (if any):			

* Session duration: 50 mins



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Sub. Code / Sub. Name: BT22075/Clinical Trials and Healthcare Policies in Biotechnology

Unit : IV

Unit Syllabus: Basics of Statistical Analysis

9 Hrs

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), Nonparametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi-square test), Null hypothesis, P values, Degree of freedom, Interpretation of P values.

Objective: Demonstrate the basic bio-statistical techniques involved in clinical research.

Session No *	Topics to be covered	Ref	Teaching Aids
28.	Definition, Application, Sample size, Importance of sample size	TB-2: Pg.No. 130–150	BB & PPT
29.	Factors influencing sample size, Dropouts	TB-2: Pg.No. 150–170 TB-2: Pg.No. 170–185	BB & PPT
30.	Statistical tests of significance	TB-2: Pg.No. 185–205	BB & PPT
31.	Type of significance tests	TB-2: Pg.No. 185–205	BB & PPT
32.	Parametric tests (students "t" test, ANOVA,	TB-2: Pg.No. 185–205	Statistical tools- PRISM Graphpad, SPSS
33.	Correlation coefficient, regression), Nonparametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi-square test)	TB-2: Pg.No. 205–235 TB-2: Pg.No. 235–260	Statistical tools- PRISM Graphpad, SPSS
34.	Null hypothesis	TB-2: Pg.No. 260–285 RB 5: Pg.No. 145–165	Statistical tools- PRISM Graphpad, SPSS
35.	P values	TB-2: Pg.No. 260–285 TB-3: Pg.No. 255–280	Statistical tools- PRISM Graphpad, SPSS
36.	Degree of freedom, Interpretation of P values.	TB-2: Pg.No. 260–285 TB-3: Pg.No. 255–280	BB & PPT
Content beyond syllabus covered (if any):			

* Session duration: 50 mins



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Sub. Code / Sub. Name: BT22075/Clinical Trials and Healthcare Policies in Biotechnology

Unit : V:

Unit Syllabus: National Health Policies**9 Hrs**

Introduction, Goal, Principles and Objectives, Policy Thrust, Mainstreaming the potential of AYUSH Tertiary Care Services, Human Resources for Health, Financing of Health Care, Collaboration with Non-Government Sector/Engagement with private sector, Regulatory Framework, Vaccine Safety Medical Technologies, Public Procurement, Availability of Drugs and Medical Devices, Improving Public Sector Capacity for manufacturing essential drugs and vaccines, Anti-microbial Resistance Health Technology Assessment, Health Surveys, Health Research, Governance, Legal Framework for Health Care and Health Pathway, Implementation Framework and way forward

Objective: To illustrate the importance of health policies.

Session No *	Topics to be covered	Ref	Teaching Aids
37.	Introduction, Goal, Principles and Objectives	TB-4:Pg.No. 5-25 RB 5:Pg.No. 8-30	BB & PPT
38.	Policy Thrust, Mainstreaming the potential of AYUSH Tertiary Care Services,	TB-4: Pg.No. 25-50 TB-2: Pg.No. 30-50	BB & PPT
39.	Human Resources for Health, Financing of Health Care, Collaboration with Non-Government Sector/Engagement with private sector,	TB-2: Pg.No. 50-75 TB-2: Pg.No. 75-95	BB & PPT
40.	Regulatory Framework, Vaccine Safety Medical Technologies, Public Procurement,	TB-2: Pg.No. 95-125 TB-2: Pg.No. 125-150	BB & PPT
41.	Availability of Drugs and Medical Devices, Improving Public Sector Capacity for manufacturing essential drugs and vaccines,	TB-2: Pg.No. 150-175	BB & PPT
42.	Anti-microbial Resistance Health Technology Assessment,	TB-2: Pg.No. 175-200 RB 5: Pg.No. 180-205	BB & PPT
43.	Health Surveys, Health Research, Governance,	TB-2: Pg.No. 200-225 RB 5: Pg.No. 205-230	BB & PPT
44.	Legal Framework for Health Care	TB-2: Pg.No. 225-250 RB 5: Pg.No. 230-255	BB & PPT
45.	Health Pathway, Implementation Framework and way forward	TB-2: Pg.No. 250-270 TB-4: Pg.No. 235-260	BB & PPT
Content beyond syllabus covered (if any):			

* Session duration: 50 mins



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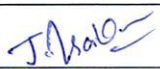
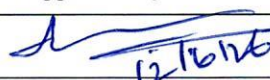
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Sub Code / Sub Name: BT22075/Clinical Trials and Healthcare Policies in Biotechnology**TEXT BOOKS**

1. Rippe J, "Lifestyle medicine", 2 nd Edition, CRC Press, Newyork, 2013.
2. Lawrence M. Friedman, "Fundamentals of Clinical Trials", Springer Science & BusinessMedia, 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.
5. National Health Policy, Ministry of Health and Family Welfare Government of India, 2017.

REFERENCE BOOKS

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.
3. Susan Halabi, Stefan Michiels, "Textbook of Clinical Trials in Oncology, A Statistical Perspective", CRC Press 2019.
4. Karl E. Peace, "Design and Analysis of Clinical Trials with Time-to-Event Endpoints", CRC Press, 2009.
5. Alice Kuruvilla, A D Paul, "Clinical Trials A Beginner's Guide", Paras Medical Publisher, 2013.

	Prepared by	Approved by
Signature		 12/06/26
Name	Dr.J.Isaivani	Prof. E. Nakkeeran
Designation	Assistant Professor	HOD - BIO
Date	12/06/2026	12/06/2026
Remarks *: If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD.		