SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY



| Department of Biotechnology | LP: BT22075<br>Rev. No: 00<br>Date: 12/06/2026 |
|---|---|
| B.E/**B.Tech**/M.E/M.Tech**: Biotechnology** **Regulation: 2022**<br>**PG Specialisation : NA**<br>**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<br>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

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**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<br>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<br>RB 5: Pg.No. 45–70 | BB & PPT |
| 13. | The role of placebo in clinical trials | TB-3: Pg.No. 190–205<br>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<br>RB 5: Pg.No. 90–120 | BB & PPT |
| 15. | Data safety monitoring boards | TB-3: Pg.No. 230–250<br>RB 5: Pg.No. 120–145 | BB & PPT |
| 16. | Responsibilities of the sponsor | TB-3: Pg.No. 250–275<br>TB-4: Pg.No. 410–440 | BB & PPT |
| 17. | CRO in the ethical conduct of clinical research | TB-3: Pg.No. 250–275<br>TB-4: Pg.No. 410–440 | BB & PPT |
| 18. | Investigator in the ethical conduct of clinical research | TB-3: Pg.No. 250–275<br>TB-4: Pg.No. 410–440 | 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: 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<br>RB 2: pg.no. 250–270 | BB & PPT |
| 20. | Trial profile | TB-2: pg.no. 540–550<br>RB 2: pg.no. 270–285 | BB & PPT |
| 21. | Presenting baseline data | TB-2: pg.no. 550–565<br>TB-3: pg.no.. 295–310 | BB & PPT |
| 22. | Use of Tables | TB-2: pg.no. 565–585<br>TB-3: pg.no. 310–330 | Experiential learning |
| 23. | Figures | TB-2: pg.no. 565–585<br>TB-3: pg.no. 310–330 | Experiential learning |
| 24. | Critical appraisal of the report | TB-2: pg.no. 585–605<br>TB-3: pg.no. 330–350 | BB & PPT |
| 25. | Meta-analysis. | TB-2: pg.no 605–630<br>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<br>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<br>TB-2: Pg.No. 235–260 | Statistical tools-PRISM Graphpad, SPSS |
| 34. | Null hypothesis | TB-2: Pg.No. 260–285<br>RB 5: Pg.No. 145–165 | Statistical tools-PRISM Graphpad, SPSS |
| 35. | P values | TB-2: Pg.No. 260–285<br>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<br>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<br>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<br>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<br>TB-2: Pg.No. 75–95 | BB & PPT |
| 40. | Regulatory Framework, Vaccine Safety Medical Technologies, Public Procurement, | TB-2: Pg.No. 95–125<br>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<br>RB 5: Pg.No. 180–205 | BB & PPT |
| 43. | Health Surveys, Health Research, Governance, | TB-2: Pg.No. 200–225<br>RB 5: Pg.No. 205–230 | BB & PPT |
| 44. | Legal Framework for Health Care | TB-2: Pg.No. 225–250<br>RB 5: Pg.No. 230–255 | BB & PPT |
| 45. | Health Pathway, Implementation Framework and way forward | TB-2: Pg.No. 250–270<br>TB-4: Pg.No. 235–260 | BB & PPT |
| **Content beyond syllabus covered (if any):** | | | |

* Session duration: 50 mins

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**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 | J.Isaivani | 12/6/26 |
| 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.