

Name of Institute: Indus Institute of Sciences, Humanities & Liberal Studies

Name of Faculty: Prof.Ghanshyam Malviya

Course code: PCR0304

Course name: Biostatistics-II

Pre-requisites: Introduction to Biostatistics in Clinical Trials.

Credit points: 4

Offered Semester: III

Course Coordinator (weeks 01 - 15)

Full name: Ghanshyam Malviya

Department with sitting location: Science & Humanities, 4th Floor Staff Room

Telephone: 9510011918

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Consultation times:

Course Lecturer (weeks 01 - 15)

Full name: Ghanshyam Malviya

Department with sitting location: Science & Humanities, 4th Floor Staff Room

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Consultation times:

Students will be contacted throughout the Session via Mail with important information relating to this Course.

Course Objectives

By participating in and understanding all facets of this Course a student will:

- To understand Biostatistics and its application in Clinical Trials

Course Outcomes (CO)

1. Learn Introduction of central tendency
2. Understand the measures of central tendency
3. Understand the measures of variability, normal distribution and measures of relationship.
4. Apply the design, meaning and significance of statistic and significance of difference between two statistics (Testing Hypothesis).
5. Type of studies and Application of statistics in clinical trial.
6. Learn Analysis and interpretation of data.

Course Outline

Introduction to Biostatistics in Clinical Trials, Data, Sample, parameters, Measures of Variability, Normal distribution, Measures of Relationship, Experimental Design, Analysis and Interpretation of Data.

Method of delivery

Unit-1- 1st July to 15th August Online Sessions, Chalk&Talk

Study time

4 hour lectures per week

Blooms Taxonomy and Knowledge retention (For reference)

(Blooms taxonomy has been given for reference)



Figure 1: Blooms Taxonomy

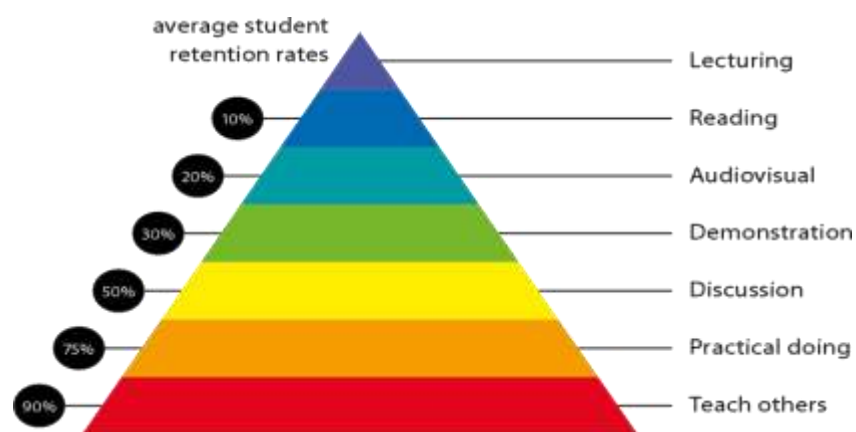


Figure 2: Knowledge retention

Graduate Qualities and Capabilities covered

(Qualities graduates harness crediting this Course)

General Graduate Qualities	Specific Department of _____ Graduate Capabilities
Informed Have a sound knowledge of an area of study or profession and understand its current issues, locally and internationally. Know how to apply this knowledge. Understand how an area of study has developed and how it relates to other areas.	1 Professional knowledge, grounding & awareness
Independent learners Engage with new ideas and ways of thinking and critically analyze issues. Seek to extend knowledge through ongoing research, enquiry and reflection. Find and evaluate information, using a variety of sources and technologies. Acknowledge the work and ideas of others.	2 Information literacy, gathering & processing
Problem solvers Take on challenges and opportunities. Apply creative, logical and critical thinking skills to respond effectively. Make and implement decisions. Be flexible, thorough, innovative and aim for high standards.	4 Problem solving skills
Effective communicators Articulate ideas and convey them effectively using a range of media. Work collaboratively and engage with people in different settings. Recognize how culture can shape communication.	5 Written communication
	6 Oral communication
	7 Teamwork
Responsible Understand how decisions can affect others and make ethically informed choices. Appreciate and respect diversity. Act with integrity as part of local, national, global and professional communities.	10 Sustainability, societal & environmental impact

Lecture/tutorial times

Lecture	Monday	10:00 – 11:00 am	Online
Lecture	Tuesday	10:00 – 11:00 am	Online
Lecture	Thursday	10:00 – 11:00 am	Online
Lecture	Friday	12:20 – 01:20 pm	Online

Attendance Requirements

The University norms states that it is the responsibility of students to attend all lectures, tutorials, seminars and practical work as stipulated in the Course outline. Minimum attendance requirement as per university norms is compulsory for being eligible for mid and end semester examinations.

Details of referencing system to be used in written work

Text books

Fundamentals of Biostatistics, -Khan, Khanum, 1994

Additional Materials

1. Basic and Clinical Biostatistics- Beth Dawson and Robert G. Trapp, 3rd edition.
2. Introductory Applied Biostatistics- Ralph B. DAgostino. Sr., Lisa M. Sullivan, Alexa S. Beiser, 2001
3. Principles and Practice of Biostatistics- Belavendra Antonisamy, Prasanna S, Prem Kumar, and Solomon Christopher, July 2017
4. Biostatistics: Basic Concepts and Methodology for the Health Sciences- Chad Lee Cross and Wayne W Daniel, 2013

ASSESSMENT GUIDELINES

Your final course mark will be calculated from the following:

Internal Exam	60%	Objectives (2-5) (40 MSE+ 20Attendance +Assignments)
Final exam (<i>closed book</i>)	40%	Objectives (1-5)

SUPPLEMENTARY ASSESSMENT

Students who receive an overall mark less than 40% in mid semester or end semester will be considered for supplementary assessment in the respective components (i.e mid semester or end semester) of semester concerned. Students must make themselves available during the supplementary examination period to take up the respective components (mid semester or end semester) and need to obtain the required minimum 40% marks to clear the concerned components.

Practical Work Report/Laboratory Report:

A report on the practical work is due the subsequent week after completion of the class by each group.

Late Work

Late assignments will not be accepted without supporting documentation. Late submission of the reports will result in a deduction of -% of the maximum mark per calendar day

Format

All assignments must be presented in a neat, legible format with all information sources correctly referenced. **Assignment material handed in throughout the session that is not neat and legible will not be marked and will be returned to the student.**

Retention of Written Work

Written assessment work will be retained by the Course coordinator/lecturer for two weeks after marking to be collected by the students.

University and Faculty Policies

Students should make themselves aware of the University and/or Faculty Policies regarding plagiarism, special consideration, supplementary examinations and other educational issues and student matters.

Plagiarism - Plagiarism is not acceptable and may result in the imposition of severe penalties. Plagiarism is the use of another person's work, or idea, as if it is his or her own - if you have any doubts at all on what constitutes plagiarism, please consult your Course coordinator or lecturer. Plagiarism will be penalized severely.

Do not copy the work of other students.

Do not share your work with other students (except where required for a group activity or assessment)

Course schedule(subject to change)

(Mention quiz, assignment submission, breaksetcas well in the table under the Teaching Learning Activity Column)

	Week #	Topic & contents	CO Addressed	Teaching Learning Activity (TLA)
	Weeks 1	Introduction to Biostatistics in Clinical Trials	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Weeks 2	Statistical principles underlying clinical trials data handling and role of Biostatistician	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Week 3	Statistical principles underlying clinical trials data handling and role of Biostatistician	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Week 4	Statistical principles underlying clinical trials data handling and role of Biostatistician	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Week 5	Concepts, types, significance and scope of statistics	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Week 6	Concepts, types, significance and scope of statistics	Learn Introduction of central tendency	Online Lecture, Assignment ,Tutorial
	Week 7	Meaning of Data, Sample, parameters, Types and levels of data and their measurements.	Understand the measures of central tendency	Chalk and talk, assignments and unit test
	Week 8	Organization and presentation of Data-Tabulation of data.	Understand the measures of central tendency	Chalk and talk, assignments and unit test
	Week 9	Frequency distribution, Graphical and tabular presentation. Mean, Median and Mode, Range, Percentiles, Average Deviation, Quartile Deviation and Standard	Understand the measures of central tendency	Chalk and talk, assignments and unit test

		Deviation Probability		
	Week 10	Characteristics and Application of Normal Probability Curve: Sampling error Correlation-Need and Meaning, Rank Order Correlation. Scatter Diagram Method, Product Moment Correlation, Simple Linear Regression Analysis and Prediction.	Understand the measures of variability, normal distribution and measures of relationship.	Chalk and talk, assignments and unit test
	Week 11	Experimental Design, Comparison in Pairs, Randomized Block Design, Latin Squares, Non Parametric test-Chisquare test, sign, Median test, Mann Whitney Test, Parameters, Cohort Studies,	Apply the design, meaning and significance of statistic and significance of difference between two statistics (Testing Hypothesis).	Chalk and talk, assignments and unit test
	Week 12	Pilot Studies, Retrospective and Prospective Studies, Epidemiological Studies. Ratios, Rates and T Score, Vital Health Statistics-Birth and Death Rates, Measures related to Fertility, Morbidity and Mortality	Apply the design, meaning and significance of statistic and significance of difference between two statistics (Testing Hypothesis). Type of studies and Application of statistics in clinical trial.	Chalk and talk, assignments and unit test
	Week 13	Analysis and Interpretation of Data: Plan for Data Analysis: Quantitative and Qualitative, Preparing Data for Computer Analysis and Presentation, Statistical Analysis, Interpretation of Data Conclusion and Generalizations, Summary and Discussion.	Learn Analysis and interpretation of data.	Chalk and talk, assignments and unit test

	Week 14	Applications of Biostatistics: Statistical Evaluation, Evaluation and Reporting, Summarizing the Clinical Database, Efficacy Data and Safety Data, Estimation,	Learn Analysis and interpretation of data.	Chalk and talk, assignments and unit test
	Week 15	Confidence Intervals and Hypothesis Testing, Integrity of Data and Computer Software Validity, Data Capture and Processing, Blinding and Randomization	Learn Analysis and interpretation of data.	Chalk and talk, assignments and unit test