# **CLINICAL TRIALS: DESIGN AND ANALYSIS**

### What will I learn?

- · Probability Distributions Probability, conditional probability, random variables and distributions, independence, expectation, moment generating functions, useful parametric families of distributions, transformation of random variables, order statistics, sampling distributions under normality, the central limit theorem, convergence concepts and illustrative applications.
- · Approaches to Quantitative Analysis in the Life Sciences Case studies of common data analytic methods used in the life sciences. The case studies are designed to help students who are interested in applications of statistical thinking to biological sciences appreciate the scope of quantitative methods, their underlying concepts, assumptions and limitations.
- Clinical Trials Design and Analysis Statistical methods and issues in the design of clinical trials and analysis of their data. Topic include clinical trial designs for phases 1-4, randomization principle and procedures, analysis of pharmacokinetic data for bioequivalence, multi-center trials, categorical data analysis, survival analysis, longitudinal data analysis, interim analysis, estimation of sample size and power, adjustment for multiplicity, evaluation of adverse events, and regulatory overview.
- Statistical Inference Data reduction principles: sufficiency and likelihood. Theory and methods of point estimation and hypothesis testing, interval estimation, nonparametric tests, introduction to linear models.
- Sampling Theory Role of sample surveys. Sampling from finite populations. Sampling designs, the Horowitz-Thompson estimator of the population mean. Different sampling methods, simple random sampling, stratified sampling, ratio and regression estimates, cluster sampling, systematic sampling.
- · Design and Analysis of Experiments Statistically designed experiments and their importance in data analysis, industrial experiments. Role of randomization. Fixed and random effect models and ANOVA, block design, latin square design, factorial and fractional factorial designs and their analysis.

## Why study Clinical Trials: Design and Analysis at NJIT?

The NJIT Department of Mathematics offers two types of courses: theoretical and practical. Graduates from this program will understand the concepts of advanced statistical techniques as well as modern day software that utilize these concepts.

#### Into what industries might holders of this program find employment?

Data Science, Consultation Services, Auditing, Analytics, Census

#### Prerequisites

Applicants should have a bachelor's degree in an engineering or mathematics-based field. Undergraduate statistics coursework and Calculus III+ expected.

#### **Related Degree Programs**

All courses in this program related entirely to the NJIT MS in Applied Statistics (https://catalog.njit.edu/graduate/science-liberal-arts/mathematicalsciences/applied-statistics-ms/)

The Graduate Certificate in Clinical Trials: Design and Analysis is a short, but dense, selection of statistical courses from NJIT's Department of Mathematical Sciences. Topics will include: probability theory, binomial distribution, regression analysis, standard deviation, stochastic processes, Monte Carlo method, Bayesian statistics, non-parametric statistics, sampling theory, and statistical techniques. The theoretical approach that begins the program comes together within the elective courses in a practical sense, from pharmokinetic data to life science studies to business-oriented time series data sets.

# Who would be suited to take this program?

The program is well suited for students with a baccalaureate degree, especially with higher level Calculus background, who are planning to pursue a statistics-oriented career in the pharmaceutical or other industries and in commercial enterprises where basic statistical skills and knowledge of contemporary methods of data analysis and modeling are required, such as computational data analytic or business intelligence positions.

# What are the Required Courses?

Code	Title	Credits
Core Courses		
Take this course:		3

MATH 662 (http://catalog.njit.edu/ Probability Distributions search/?P=MATH%20662)

Electives - Choose three (3) courses:

MATH 615 (http://catalog.njit.edu/ search/?P=MATH%20615)	Approaches to Quantitative Analysis in the Life Sciences
MATH 654 (http://catalog.njit.edu/ search/?P=MATH%20654)	Clinical Trials Design and Analysis
MATH 665 (http://catalog.njit.edu/ search/?P=MATH%20665)	Statistical Inference
MATH 698 (http://catalog.njit.edu/ search/?P=MATH%20698)	Sampling Theory
MATH 699 (http://catalog.njit.edu/ search/?P=MATH%20699)	Design and Analysis of Experiments

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