IICRT INTERNATIONAL INSTITUTE FOR CLINICAL RESEARCH & TECHNOLOGY

DIPLOMA IN CLINICAL BIOSTATISTICS

CONTACT US:

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PLEASE SET AN APPOINTMENT BEFORE DROPPING BY.

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This course helps to prepare analysis and report for clinical trial data using advanced programming methods. And the program has been developed to use standard statistical analysis software to handle human subject trial data. This program gain confident to every graduate for get involved in clinical research & development work with biostatistics and programming skills.

Who can Learn:

- Any UG / PG life-science degree graduate (final year or passed out)
- Any clinical professionals, Biostatistician and database developer
- Basic computer handling, MS Word and Excel Knowledge preferred.

Course Contents:

- **Clinical Research Essential**
  - •History of clinical research
  - •Clinical Research and It's types phases
  - •Clinical Research – Study Design
  - •Trial Process
  - •Regulatory body Process

- **Global Regulatory Compliance**
  - •Regulatory Requirements & it's body Process
  - •Good Clinical Practice (GCP)
  - •Good Clinical Data Management Practice
  - •21 CFR Part 11: Electronic Records and Signature
  - •CDISC Introduction
  - •Computer System Validation

- **Biostatistics for Clinical Trials**
  - •Introduction to Biostatistics – Scope & Limitation
  - •Epidemiological Study design- Descriptive, Analytical and Experimental
  - •Epidemiological Measure.
  - •Statistical Analysis Plan

- **Clinical Trial Programming**
  - •SAS programming tools & process.
  - •Understanding SAS syntax.
  - •Understanding SAS data & libraries.
  - •Importing external data into SAS.
  - •Data Manipulation Techniques.
  - •Combining and merging datasets.
  - •Enhancing reports with titles, footnotes, and labels
  - •Creating frequency reports
  - •Creating summary statistics reports
  - •Exporting data & reports
  - •Introduction to Macro Programming
  - •Macro Variables, Definition, Macro Statement
  - •Data Step and SQL Interfaces for Macro Program
  - •Advance Macro Programming Technique
  - •Creating Detail and summary report using REPORT and TABULATE Procedure
  - •Output delivery system
  - •Introduction to ANOVA, Regression and Logistic Regression
  - •More complex Linear model
  - •GLM and TTEST PROCEDURE

- **CDISC Essentials**
  - •What is CDISC and Why Standards?
  - •Available CDISC Standards and models
  - •How SAS supports CDISC Model
  - •FDA – Submission Process.

- **Internship**
  - •Clinical Trial Programming – Data Validation
  - •Clinical Trial Programming – Reporting
  - •Clinical Trial Programming – Data Analysis
  - •Clinical Trial Programming – Database Process
  - •Clinical Trial Programming – E-submission