AL105:
Biostatistics for Non-Statisticians

Training Description:

This intensive training is designed as an introduction to the statistical principles that form the basis for the design and analysis of research investigations in pharmaceutical and medical device studies.

The course will concentrate on the philosophy and understanding of the statistical principles required in conducting sound scientific investigations with an interdisciplinary approach to trial design and analysis. It includes discussion of the topics one considers in the Statistical Analysis Plan (SAP). It will not simply present statistical formulae. Thus, the lectures are oriented toward professionals having little or no formal training in statistics or mathematics.

Training Objective:

By the end of the training, participants will be able to:

- ✓ Understand the concepts and statistical methods required in biological and health science research
- ✓ Interpret results related to design and analysis issues as routinely presented in the scientific literature and clinical trials

Training Designed for:

This course is intended for those individuals within the pharmaceutical, biotech and device industries including R&D Managers, Medical Investigators, Basic and Clinical Research Scientists, Clinical Research Associates and those involved in regulatory affairs.

Training Program:

FIVE DAYS:

- ❖ PRE-TEST
- ❖ Introduction
- ❖ Statistical Concepts and Terminology
  - Population, sample, nominal, ordinal, continuous data
- ❖ Statistical Measures and Descriptive Statistics
  - Central tendency (average or mean, median, mode), dispersion measures such as range, variance, standard deviation, coefficient of variation, unbiased estimate
- ❖ Graphical Techniques
  - Histograms, bar charts, box plots
- ❖ Distributions
  - Normal, t-distribution, skewed distribution
- ❖ Inferential Statistics
  - Point and interval estimates of the mean and variance of a population. Hypothesis testing for the mean and variance of a population
- ❖ Risk Assessment
  - Relative risk, odds ratio, Bayes risk
- ❖ Defining a Sound Scientific Study
  - Selection criteria to statistical consideration
- ❖ Single Therapy Protocols
  - Phase I and Phase II clinical trials, sample size and analyses, simple regression technique

- Comparative Studies
  - Defining appropriate study hypotheses, study objectives, defining efficacy measures and endpoints (response), sample size considerations, quantitative measures, analyses (continuous and discrete data), case control studies
- Data Presentation
  - Interpretation and discussion of results from actual clinical data computer output for categorical and continuous endpoints, p-values, statistical significance, risk measures
- Multiple Treatment Studies
  - Analysis of Variance (ANOVA), multiple regression Multiple Treatment Clinical Protocols: Phase III protocol sample size and comparative analyses (response and survival techniques)
- Equivalence and Non-Inferiority Studies
  - Point and interval testing for equivalence, Non-inferiority and superiority graphical technique
- Meta-Analytic Techniques
  - Presentation of individual patient vs. literature based meta-analyses, statistical tests of homogeneity and pooled effect size
- Course Conclusion
- POST-TEST and EVALUATION

Training Requirement:

"**Hand's on practical sessions, equipment** and **software** will be applied during the course if required and as per the client's request."

Please note that the above topics can be amended as per client's learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Methodology:

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

Internationally recognized certificate(s) will be issued to each participant who completed the course.

Training Fees:

As per the course location - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01st of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

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Training Timings:

Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:30	Recess (Prayer Break & Lunch)
13:30 - 15:00	Last Session

For training registrations or in-house enquiries, please contact:

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Training & Career Development Department