AL106:
Advanced Biostatistics for Non-Statisticians

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Training Description:

This pharmaceutical and medical device training course begins with a brief introductory discussion that will introduce and outline the types of clinical investigations conducted. This includes Phase II (non- randomized and randomized) and Phase III randomized clinical trials. It will emphasize the principles of clinical investigations and the issues to be addressed in the remainder of the course. Also, the concept of the p-value and power will be reviewed.

This course is designed as an overview to the statistical principles that go beyond the basics for the design and analysis of research investigations in pharmaceutical and medical device studies. This biotech training will concentrate on the philosophy and understanding of the statistical requirements used in conducting sound scientific investigations. It will not simply present statistical formulae. Thus, the lectures are oriented toward professional who have familiarity with basic principles of Biostatistics and/or Statistical Analysis or at least have attended the basic course "Biostatistics for Non-Statisticians."

Training Objectives:

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

- ✓ Have an in-depth understanding of the concepts and statistical methods required in pharmaceutical, biological, medical device and other health science research
- ✓ Interpret results related to design and analysis issues of modern statistical techniques as routinely presented in the scientific literature and clinical trials
- ✓ Understand topic definitions followed by a discussion of their impact on clinical studies and the procedures for handling them in context, with many specific examples used

Training Designed for:

This course is intended for those individuals within the pharmaceutical, biotech and medical device industries including Medical Investigators, Basic and Clinical Research Scientists, Clinical Research Associates and those involved in regulatory affairs who have taken the introductory course "Biostatistics for Non–Statisticians" or are familiar with the basic conduct of clinical trials and wish to pursue a deeper understanding of statistical principles.

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."

This training course is available upon request in English or Arabic, virtual online live or face to face public/inhouse. Contents can be adapted to your specific wishes. It is therefore possible to focus on specific modules of the training course as per client's learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Program:

FIVE DAYS:

- ❖ Multiple Primary and Secondary Endpoints

- Reasons for composite endpoints, types of multiplicity encountered, design issues, examples of statistical procedures for addressing multiple endpoints, weighting of hypotheses, multiple stage testing procedures

❖ Missing Data in Clinical Trials
- Types of missing data, mechanisms of missing data (e.g. missing completely at random, missing at random, non-ignorable), consequences of missing data, simple and multiple imputation examples

❖ Adaptive Designs
- Midway correction techniques, preservation of Type I and Type II errors, two and three stage design examples (randomized and non-randomized), comparison to group sequential (interim analysis only) designs

❖ Competing Risk Analysis
- Definitions of types of competing risks (CR), Types of trials with CR, the different statistical approaches to CR (advantages, disadvantages), several examples comparing performance of these approaches

❖ Introduction to Bayes Analysis of Clinical and Epidemiological Studies
- Explanation of Bayes methods, Comparison of Bayes methods to traditional statistical approaches to clinical studies such as screening designs, drug development analysis, equivalence studies. Time to event (survival) prediction using Bayes methods. Propensity Scoring in Clinical Trials: Definition and popularity of propensity scoring, the need for propensity measures in place of large sets of covariates, Types of propensity scoring (modeling, matching, stratification) and detailed data examples of each

❖ Statistical Approaches to High Density Data Sets
- Classification techniques according to diagnostic or treatment assignment outcomes, decision trees, bootstrap forest and boost trees, the role of ROC curves, recent methodology for analysis gene expression data

❖ Brief Introduction to Meta-Regression
- Methods of meta-regression beyond the usual meta-analysis to determine variables or covariates influencing outcome other than the main treatment /intervention effect, techniques combining both literature data and raw data will be discussed

❖ Course Conclusion
❖ POST-ASSESSMENT and EVALUATION

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, Gamification, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

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

Training Fees:

TBA 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.

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 - 13:00	Recess (Prayer Break & Lunch)
13:00 - 14:00	Last Session

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

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