ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

CANCELLATION POLICY

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CFPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

HOW TO REGISTER

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

PAYMENT

$2650.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CFPIE.

COURSE DESCRIPTION

The following include but are not limited to topic areas to be discussed:

• Basic statistical terminology needed to effectively communicate with and understand your statistical colleagues
• The statistical essentials required to initiate a research investigation and plan a clinical trial
• Research questions in statistical terms and bias reducing techniques in planning a clinical trial
• Sample size considerations to insure accuracy of conclusions in clinical trials to determine treatment efficacy. A discussion of ethical considerations in sample size planning
• Examination of Phase I (adverse events) and dose response studies
• Discussion of statistical techniques to compare experimental approaches or treatment efficacy with a focus on superiority outcomes
• An introduction to interim and group sequential designs as well as futility analysis

The third day of course will cover more complex issues in research investigations and clinical trials. Topics will include:

• Association studies including correlation and regression analysis with clinical applications to multiple intervention strategies
• Examination of Phase II and III clinical trials analysis. Comparative studies will contrast superiority, equivalence and non-inferiority approaches to design and analysis
• Survival analysis and discussion of related techniques (hazard ratio, multivariate Cox modeling)
• Gaining information from multiple studies by meta-analysis and the challenges of combining information
INSTRUCTOR CREDENTIALS

Dr. Al Bartolucci is Emeritus Professor of Biostatistics at the University of Alabama where he also serves as a Senior Scientist at the Center for Metabolic Bone Diseases, AIDS Research Center and Cancer Center.

He previously served as Chairman of the Department from 1984 through 1997. He has also taught Statistical Software courses involving Data Exploration, ANOVA/Regression and Design of Experiments. His teaching experience includes areas such as, Clinical Trials, Survival Analysis, Multivariate Analysis, Regression Techniques and Environmental/Industrial Hygiene Sampling and Analysis, Bayesian Statistics, and Longitudinal Data Analysis.

Dr. Bartolucci received his PhD in Statistics from the State University of New York at Buffalo and his MA in Mathematics from Catholic University, Washington DC, and his BA in Mathematics from Holy Cross.

LEARNING OBJECTIVES

Those completing this course will have an understanding of the concepts and statistical methods required in biological and health science research. They will be able to interpret results related to design and analysis issues as routinely presented in the scientific literature and clinical trials.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $255/night if booked 4 weeks in advance).
DoubleTree by Hilton London - Victoria (CPIE room rate of £199.00/night if booked 4 weeks in advance)

FIRST DAY

First Day

- 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.

SECOND DAY

Second Day

- 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.

THIRD DAY

Third Day

- 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

WHO SHOULD ATTEND

This three-day course 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 focus of topics will benefit 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.

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.