

# BIOSTATISTICS FOR THE NON-STATISTICIAN

Learn Biostatistics for the Non-Statistician

The focus of the seminar is to give you the information and skills necessary to understand statistical concepts and findings as applies to clinical research, and to confidently convey the information to others.

#### **LEARNING OBJECTIVES**

#### The goal of this seminar is to teach you enough statistics to:

- Understand the statistical portions of most articles in medical journals.
- Do simple calculations, especially ones that help in interpreting published literature.
- Avoid being misled by foolish findings.
- Knowledge of which test when, why, and how.
- Perform simple analyses in statistical software.
- · Communicate statistical findings to others more clearly.

#### WHO WILL BENEFIT

- Physicians
- · Clinical Research Associates
- Clinical Project Managers/Leaders
- Sponsors
- Regulatory Professionals who use statistical concepts/terminology in reporting
- Medical Writers who need to interpret statistical reports
- Clinical research organizations, hospitals, researchers in health and biotech fields.

## SEMINAR INCLUDES

Certificate, PDF copy of the Handouts, Q/A Session, Live Instructor led 3 Days Web Seminar & Statistical Analysis Plan Template provided by the faculty



### BIOSTATISTICS FOR THE NON-STATISTICIAN

#### **AGENDA DAY 1**

#### **Session 1: Why Statistics**

- · Do we really need statistical tests?
- · Sample vs. Population
- · I'm a statistician not a magician! What statistics can and can't do
- Descriptive statistics and measures of variability

#### Session 2: The many ways of interpretation

- Confidence intervals
- · p-values
- Effect sizes
- · Clinical vs. meaningful significance

#### Break - 10 mins

#### Session 3: Types of Data and Descriptive Statistics

- · Levels of data: Continuous, Ordinal, Nominal
- Normal distribution and it's importance
- Graphical representations of data
- Data transformations, when and how

#### **Break 10 mins**

#### Session 4: Common Statistical Tests

- · Comparative tests
- · Simple and Multiple regression analysis
- Non-parametric techniques

#### O&A

#### **AGENDA DAY 3**

#### **Session 1: Other Tests**

- Non-Parametric tests
- Test for equivalency
- Test for non-inferiority

#### **Break 10 mins**

#### **Session 2: Power and Sample Size**

- Theory, steps, and formulas for determining sample sizes
- Demonstration of sample size calculations with GPower software

#### Session 3: How to Review a Journal Article

- · General steps on article review
- Determining the quality of a journal or journal article
- Looking for limitations (all studies have them)

#### **Break 10 mins**

#### Session 4: Developing a Statistical Analyis Plan

- Using FDA (for the U.S. audience) or MHRA (for U.K. audience) guidance as a foundation, learn the steps and criteria needed to develop a statistical analysis plan (SAP)
- . An SAP template will be given to all attendees

#### **AGENDA DAY 2**

#### **Session 1: Logistic Regression**

- · When and why?
- · Interpretation of odd ratios
- Presentation of logistic regression analysis and interpretation
- · Fun with contingency tables

#### **Session 2: Survival Curves and Cox Regression**

- · History, theory, and nomenclature of survival analysis
- · Kaplan-Meier Curves and Log Rank Tests
- Proportional Hazards
- · Interpretation of hazard ratios
- Presentation of KM curves and Cox regression analysis and interpretation

#### **Break 10 mins**

#### **Session 3: Bayesian Logics**

- · A different way of thinking
- Bayesian methods and statistical significance
- · Bayesian applications to diagnostics testing
- · Bayesian applications to genetics

#### **Break 10 mins**

#### **Session 4: Systematic Reviews and Meta-Analysis**

- · Why perform a systematic reviews and/or meta-analysis?
- A bit of history and reasoning for systematic reviews and/or meta analysis
- · Terminology
- · Steps in performing a Systematic Review
- · Steps in performing a Meta-Analysis



#### **REGISTRATION FORM**

| Name         | <u>Email</u> |          |  |
|--------------|--------------|----------|--|
| Organization | Department   | Position |  |
| Phone        | Mobile       |          |  |

#### Register Online At www.worldcomplianceseminars.com

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#### **Terms And Condition**

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.