

2-day In-person Seminar:

Introduction to Adaptive Design for Clinical Trials

-  Philadelphia, PA
-  November 15th & 16th, 2018
-  9:00 AM to 6:00 PM



Elaine Eisenbeisz

Owner and Principal Statistician, Omega Statistics

Elaine Eisenbeisz, is a private practice statistician and owner of Omega Statistics, a statistical consulting firm based in Southern California. Elaine has over 30 years of experience in creating data and information solutions for industries ranging from governmental agencies and corporations, to start-up companies and individual researchers.

In addition to her technical expertise, Elaine possesses a talent for conveying statistical concepts and results in a way that people can intuitively understand.

Overview :

This 2-day seminar includes an overview of Adaptive Design, and an emphasis in group sequential design, sample size re estimation, and Phase II/III Adaptive Seamless Designs.

The role of statistics in clinical trials incorporates the tools used to develop a robust study, minimize bias, and assess efficacy of new treatments as relates to comparison to competing therapies.

Randomized clinical trials remain the standard for clinical research. However, the cost of a traditional randomized controlled trial especially in large sample sizes and long study duration, are limiting factors of innovation in the pharmaceutical and medical device arenas. A trial with an adaptive design can often result in lower costs and more efficiency by making use of interim analyses with data accumulated during the course of a trial to modify a study, without compromising validity and integrity. Adaptive designs also allow for checking trial assumptions and progress before the conclusion of the study. Studies can be adapted for dose response, patient accrual, and early stopping for futility or patient safety concerns.

Price

Price: \$1,295.00

(Seminar for One Delegate)

Register now and save \$200. (Early Bird)

Register for 5 attendees

Price: \$3,885.00 You Save: \$2,590.0 (40%)*
~~\$6,475.00~~

Register for 10 attendees

Price: \$7,122.00 You Save: \$5,828.0 (45%)*
~~\$12,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Agenda:

Day One

Lecture 1(90 Mins):

Introduction

- The What, Why, and When of Adaptive Design
- Logic and Terminology of Adaptive Design
 - Rules of Allocation, Sampling, Stopping, Decisions
 - Flexible aspects of Adaptive design
- Overview of Types of Adaptive Designs
 - Investigate phases
 - Confirmatory phases

Lecture 2(90 Mins):

Group Sequential Design

- Interim Analysis considerations
- Prematurely stopping a trial due to:
 - Safety concerns
 - efficacy or futility

Lecture 3(90 Mins):

Statistical Methods for Group Sequential Designs

- Maximum information and information fractions
- Pocock and O'Brien Fleming boundaries
- Alpha spending
- Covariate Adjustments
- Enrichment Design

Lecture 4(90 Mins):

Sample Size Re-Estimation (SSR)

- Why would we want to re-assess the sample size?
 - Uncertainty in Assumptions and/or available information
 - Underpowered Study
- Protecting the Study Blind
- Statistical Considerations of SSR
 - Adaptation Rules: Effect Size Ratio
 - Adaptation Rules: Conditional Power
 - Adjustment of point estimates, confidence intervals, p-value

Day Two

Lecture 1(90 Mins):

Phase II/III Adaptive Seamless Designs: Overview and Applications

- Why an Adaptive Seamless Design?
- Terms and Reasoning
 - Dose Selection
 - Treatment Pruning
- When and When Not to Use Adaptive Seamless Design
- Special Considerations for Adaptive Seamless Design

Lecture 2(90 Mins):

Phase II/III Adaptive Seamless Designs: Statistical Methods

- Phase II/III Adaptive Seamless Designs: Statistical Methods
- Simes procedure to control multiplicity
- Inverse Normal Method
- Simulation Testing for Power Comparison

Lecture 3(90 Mins):

Practical Procedural and Regulatory Issues of Adaptive Design

- Concerns of Validity, Bias, Robustness of the Study
- Planning for an Adaptive Study
- Working with Regulatory Agencies
- Concerns and Controls for Repeated Testing (Multiplicity)
- Monitoring and Decision Making in an Adaptive Study

Lecture 3(90 Mins):

Case Study and Protocol Examples, Q&A/Discussion

- An open review and discussion of adaptive trials in which researchers incorporated the four adaptive design rules.
- Examples of protocol and statistical analysis plan sections using an adaptive trial framework
- Question and Answer Session



Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

- 1 Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
- 3 PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
- 4 Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

- 1 Learning Objectives
- 2 Participation certificates
- 3 Interactive sessions with the US expert
- 4 Post event email assistance to your queries.
- 5 Special price on future purchase of web based trainings.
- 6 Special price on future consulting or expertise services.
- 7 Special price on future seminars by GlobalCompliancePanel.
- 8 Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
- 9 Networking with industry's top notch professionals

Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel

161 Mission Falls Lane, Suite 216,

Fremont, CA 94539, USA

Toll free: +1-800-447-9407

Fax: 302 288 6884

Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel