

WSS Short Course

Adaptive Design: Overview, Hurdles, and Examples

Date: Tuesday, November 21, 2017

Time: 9:00 am – 3:30 pm

Instructor: Dr. Christopher Coffey

Place: Bureau of Labor Statistics

Conference rooms 1-3, 2 Massachusetts Avenue NE, Washington, DC

Course Content:

In recent years, there has been substantial interest in the use of adaptive or novel randomized trial designs. Adaptive clinical trial designs provide the flexibility to adjust aspects of the design of a clinical trial based on data reviewed at interim stages. Although there are a large number of proposed adaptations, all generally share the common characteristic that they allow for some design modifications during an ongoing trial. Unfortunately, the rapid proliferation of research on adaptive designs, and inconsistent use of terminology, has created confusion about the similarities, and more importantly, the differences among the techniques. Furthermore, the implementation of adaptive designs to date does not seem consistent with the increasing attention provided to these designs in the statistical literature. This course will attempt to clarify some of the confusion surrounding the use of these methods, as well as provide examples where they have been used in the past. The course will provide some clarification on the topic and describe some of the more commonly proposed adaptive designs. The course will also provide a more in-depth discussion of the theory and implementation of adaptive designs in real-world settings. The presenter will draw from several recent examples of studies implementing adaptive designs, and attempt to address the strengths and weakness of the approaches used. Finally, the course will focus on some specific barriers that impede the use of adaptive designs in the current environment, summarize the results of a couple of recently completed surveys to assess the interest and attitudes of the clinical trials community in general with respect to adaptive designs, and discuss future work that is needed in order to ensure that investigators can achieve the promised benefits of adaptive designs.

About the Instructor:

Dr. Coffey joined the faculty at the University of Iowa in fall 2009 as a Professor in the Department of Biostatistics and became the Director of the CTSDMC in August 2010. He received his PhD in biostatistics from the University of North Carolina at Chapel Hill in 1999 and has nearly 20 years of experience providing data management and statistical support to clinical trials. Dr. Coffey serves as the PI of the DCC for several large clinical studies, including the NINDS-funded NeuroNEXT Network. Dr. Coffey also serves as the head of the Statistics Core for the Parkinson's Progression Markers Initiative, and is co-PI of the NINDS-funded Clinical Trials Methodology in Neurology short course. Dr. Coffey has served as the primary statistician for multi-site trials in Huntington's disease, hypertension, multiple sclerosis, myasthenia gravis, obesity, pediatric migraine, spinal muscular atrophy, stroke, and traumatic brain injury. He is a past member of the NINDS NSD-K clinical trials study section, a Fellow of both the Society Clinical Trials and

American Statistical Association, serves on a number of Data and Safety Monitoring Boards. Dr. Coffey has published extensively in the areas of adaptive designs, missing data, model validation, and general clinical trial design.

Course Schedule:

8:15 - 9:00 Coffee, breakfast, and check in

9:00 - 9:15 **Introduction & Welcome**

9:15 – 9:45 **Overview of Adaptive Designs**

9:45 – 10:30 **Types of Adaptive Designs – “Learning Stage” Adaptations**

10:30 - 10:45 Break

10:45 – 12:00 **Types of Adaptive Designs – “Confirming Stage” Adaptations**

12:00 - 1:00 Lunch (provided)

1:00 - 1:45 **Types of Adaptive Designs – “Confirming Stage” Adaptations (cont.)**

1:45 – 2:15 **Good Practices & Barriers for Use of Adaptive Designs**

2:15 - 2:30 Break

2:30 – 3:15 **Surveys on Use of Adaptive Designs**

3:15 – 3:30 **Course Summary & Open Discussion**

Advance registration: In addition to your RSVP here, please go to <https://www.eventbrite.com/e/wss-short-course-adaptive-design-overview-hurdles-and-examples-tickets-38586435066> to register and pay for the class. Online registration will close on November 18, 2017; earlier if the course fills up.

Registration Fee:

Full-time students (at most 8): \$62.49 advance, \$80 at the door

WSS members: \$185.49 advance, \$200 at the door

All others: \$216.24 advance, \$240 at the door

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