

**Session: Statistical modeling with biomedical applications**

**Organizer: Carolina Euán**

**Chair: Israel Martinez-Hernandez**

The statistical inference has a crucial impact on biomedical applications. From a medical perspective, statistics appear since designing the clinical trials to analyzing the final output data. Biostatistics is a branch of statistics that specialize in responding to questions and problems in medicine, public health or biology. In this session, we present some examples of the interaction between statistics and medical studies, with a particular emphasis on the challenges, limitations, and open problems.

**Tim Ramsay, Ph.D.**

**Senior Scientist, Clinical Epidemiology Program**

**Ottawa Hospital Research Institute**

*Title: P-values have no place in non-inferiority clinical trials*

While the goal of the non-inferiority trial design is typically described as “to demonstrate that a novel treatment is not inferior to a standard treatment,” most non-inferiority trials do not have that goal. The majority of trials using the non-inferiority design are actually trying to demonstrate that a novel treatment is better than placebo, but in a context where it is not ethically acceptable to randomize patients to a placebo because of the existence of a standard, effective treatment. The p-value is an appropriate measure to interpret the results of such trials, but this type of design should more accurately be described as an “active-control efficacy design.” In true non-inferiority trials, the concept of non-inferiority is intrinsically subjective and each user of the trial results must make his or her own judgement about whether or not the novel treatment is truly non-inferior to the standard. Providing a confidence interval for the difference between the two treatments will allow a user to make this judgement in an informed manner. Simply providing a p-value will not. This talk will introduce the non-inferiority design, will explain the difference between non-inferiority and active control, and will argue that these two different objectives should be analyzed very differently.

**F. Javier Rubio, Ph. D.**

**Lecturer in [Statistics](#)**

**King's College London**

*Title: Net survival models for cancer epidemiology: The Good, The Bad, and The Ugly*

In the first part of the talk, I will discuss the "relative survival" framework, the idea of "excess hazards" modeling, and the concept of "net survival" (which is the main quantity of interest in descriptive cancer epidemiology). I will present a parsimonious hazard regression model based on the combination of a general hazard structure and a flexible parametric baseline hazard. This hazard structure contains, as particular cases, proportional hazards, accelerated hazards, and accelerated failure time structures. In the second part of the talk, I will discuss a challenge in the context of excess hazards modeling, which is related to the estimation of individual hazards, associated to other causes of death, based on insufficiently stratified life tables. I will present a possible solution to this problem using a parametric correction based on a frailty hazard regression model. I will conclude with a real-data application and a discussion about the challenges in using the relative survival framework in cancer epidemiology.

**Hernando Ombao, Ph.D.**  
**Professor of Statistics**  
**King Abdullah University of Science and Technology**  
**Saudi Arabia**

*Title: Statistical Methods for Analyzing Brain Signals  
in a Rat Stroke Experiment*

In this talk we will discuss the problem of analyzing brain signals recorded in a rat stroke experiment. The main goal in this study is to understand the brain response to a shock (e.g., a stroke) and to identify the impact of certain interventions (e.g., stimulation of whiskers) on the outcome of stroke. We will present statistical models that capture changes in the oscillatory patterns of brain signals resulting from the stroke and methods for comparing the effects of different interventions on brain signals.

This work is in collaboration with the Biostatistics Research Group at KAUST and the Frostig laboratory at UC Irvine.

**Carolina Euan, Ph. D.**  
**Post Doctoral fellow**  
**King Abdullah University of Science and Technology**  
**Saudi Arabia**

*Title: Coherence-based Clustering for Visualization of Brain Connectivity*

*Data visualization is crucial for complex-large data sets. Brain data is an example of high temporal resolution time series where the identification of patterns is very challenging. In this talk, we introduce the hierarchical cluster coherence (HCC) method for brain signals, a procedure for characterizing connectivity in a network by clustering nodes or groups of channels that display a high level of coordination as measured by "cluster-coherence." While the most common approach to measuring dependence between clusters is through pairs of single time series, our method proposes cluster coherence which measures dependence between whole clusters rather than between single elements. Thus it takes into account both the dependence between clusters and within channels in a cluster. The identified clusters correspond to connected brain regions with synchronized oscillatory activity.*