### **PIPGES · WEBINARS**

# AUG · 27 2021

## 02:00 PM

# The video call link will be available at:

https://tiny.one/rogatko

Interinstitutional Graduate Program in Statistics (PIPGES) of Federal University of São Carlos with University of São Paulo promotes seminars groups (temporarily webinars, due to pandemic issues) of researches involving Probability, Statistics, Machine Learning etc. Our interest, among other things, is to stimulate the sharing of knowledge, as well as the connection between members of the program and researchers in other institutions.

#### **Organizer**

Michel H. Montoril, Department of Statistics, Federal University of São Carlos.

### EVALUATING TREATMENT TOLERABILITY IN CANCER CLINICAL TRIALS USING THE TOXICITY INDEX

The seminar will present the results of two papers. First, we examine new strategies for understanding treatment toxicity applied to existing data from a large randomized clinical trial (NSABP-R04). Using new statistical approaches and graphical displays to summarize the toxicity data, we demonstrate how one can optimize the use of available information and provide a more complete and accurate account of which patients are at greatest risk for toxicity at the completion of a trial. We show that the Toxicity Index (TI) contains more information than other toxicity analysis methods by accounting for both the multiplicity and severity of toxicities, without losing the natural interpretability of the maximum grade approach. This added information provides greater power to examine comparisons across treatment types when compared to the maximum grade and average toxicity approaches, resulting in the least number of patients required to detect differences between treatments, and consequently saving trial resources and time (Gresham et al. 2020). Second, in Razaee et al., (2020), we construct a solid foundation on mathematical and statistical properties of the TI. We introduce the concept of a total ordering, referred to as the T-order, that allows for comparing adverse event (AE) data based on how frequently samples exhibit extreme grades. Since the T-order is a total order, it induces a full ranking among patient toxicity data, called the T-rank. This allows one to fully rank subjects (or treatments). The T-rank is relevant to drug tolerability trials where one wants to emphasize differences in extreme toxicity. The ranking also is useful in any application where variations in the extreme scores among subjects or treatments are of concern, and we are studying its application to the analysis of patient reported outcome measures. By evaluating the asymptotic relative efficiency of three summary measures, TI, maximum grade, and average grade, we showed that the TI is more efficient than the maximum and much more efficient than the average to compare patient treatment tolerability.

#### **SPEAKER**

André Rogatko · Cedars Sinais Medical Center – UCLA

#### BIO

André Rogatko is the founding director of the Biostatistics and Bioinformatics Research Center at the Samuel Oschin Comprehensive Cancer Institute, Cedars Sinai Medical Center (CSMC), Los Angeles, CA. He is also Adjunct Professor at the Department of Medicine, David Geffen School of Medicine, UCLA, CA. He earned his doctorate degree in Genetics and Statistics, "summa cum laude," from São Paulo University in Brazil in 1983. He has published several peer-reviewed articles, book chapters and computer applications in biostatistics and genetic epidemiology.

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