UCONN
UNIVERSITY OF CONNECTICUT

Department of Statistics

Presents the

Robert W. Makuch Distinguished Lecture in Biostatistics

Featuring

Donald Berry, Professor
Department of Biostatistics
University of Texas
M.D. Anderson Cancer Center

The Bayesian Revolution in Medical Research

ABSTRACT

Randomization was introduced into clinical trials by Bradford Hill in the 1940s. The RCT was revolutionary. It changed the stuff of medicine from case studies and expert opinion into a real science. The RCT became the gold standard. It was so revered that nobody wanted to change it or let others change it. As a consequence the RCT has remained pretty much the same over the last 80 years. Until now.

Bayesians have always thought they knew better. But only recently have Bayesians made inroads into clinical trial design, taking the RCT to new levels. I will explain why and how this happened. I will give examples of clinical trials in the new millennium. I will focus on adaptive basket trials and adaptive platform trials because they seem to be the niche most clearly having a role for the Bayesian approach. Both belie the old saw, “Keep it simple, stupid.” In medicine at least, KISS will come to mean, “Keep it simple and stupid."

DATE: Wednesday, April 3, 2019
TIME: 4:00 p.m.
PLACE: Chemistry Building – Room A203
https://ait.uconn.edu/live-streaming/

Coffee will be served at 3:00 p.m. in the Noether Lounge (AUST 326)

This colloquium is sponsored by the New England Statistical Society (NESS)

College of Liberal Arts and Sciences
Department of Statistics
215 GLENBROOK ROAD, UNIT 4120
STORRS, CT 06269-4120
PHONE 860.486.3413
FAX 860.486.4113
www.stat.uconn.edu

Donald Berry is professor in the Department of Biostatistics of the University of Texas M.D. Anderson Cancer Center. He received his Ph.D. in statistics from Yale University and has served on the faculty the University of Minnesota and Duke University. He has held endowed positions at Duke and M.D. Anderson. He has authored many books on biostatistics and over 400 peer-reviewed articles. He is a Thomson Reuters Highly Cited Researcher in recognition of ranking among the top 1% of most cited researchers in Clinical Medicine. He has received numerous research grants from the NIH and NSF and is Fellow of the American Statistical Association, the Institute of Mathematical Statistics, and the International Society of Bayesian Analysis. He has designed many innovative clinical trials in cancer and in virtually every other therapeutic area, including adaptive Bayesian trials. He is founder and co-owner of Berry Consultants, a company that has designed and helped run innovative trials for pharmaceutical companies, medical device companies, and for international consortia in Alzheimer's disease, cancer, Ebola, sepsis, community-acquired pneumonia and other diseases.

Robert Makuch is a Professor in the Department of Biostatistics at the Yale School of Public Health and Director of the Regulatory Affairs Track. A graduate of the University of Connecticut (BA), University of Washington (MA – mathematics), and Yale University (MPhil, PhD), Professor Makuch worked at the National Cancer Institute (NCI) and the World Health Organization's International Agency for Research on Cancer early in his career. He also worked for six months at the National Cancer Research Center in Tokyo, Japan.

He also was heavily involved in HIV research from the mid 80's through the early-mid 90's. He participated on the data monitoring committee for the original AZT vs. placebo randomized clinical trial in AIDS patients, and served on numerous committees for the NCI and the National Institute of Allergy and Infectious Diseases. He also worked closely with the Food and Drug Administration (FDA), developing and implementing more than 200 HIV studies. He also served as a Special Government Employee (SGE) to the FDA. He returned to Yale in 1986, and has worked extensively on methodologic issues in clinical trials and large population-based studies since. Another area of current interest involves detection of rare adverse drug events, especially in the post-marketing environment.

These areas of methodologic research evolved as a result of his continued interest (since the mid 1980s) in regulatory affairs science. In addition, Makuch developed a regulatory affairs track at YSPH for graduate and post-doctoral level students, and over the past 10 years has been the leader of more than 25 training programs for senior delegations of the Chinese Food and Drug Administration. His areas of medical application include cancer, HIV, arthritis, and cardiovascular disease.

In 2003, Makuch received the American Statistical Association Fellow Award for his numerous contributions to the field. In 2008, Makuch was received a Distinguished Alumni Award from the University of Connecticut. In 2012, Makuch was nominated to serve on the University of Connecticut Dean's Advisory Board for the College of Liberal Arts and Sciences. He also has been a decades-long member of Phi Beta Kappa. He also developed a 5-year biostatistics training program in Japan, in collaboration with the Japanese government. His primary research interests continue to be methodologic issues in the design, conduct, analysis, and interpretation of clinical and large-population/epidemiologic studies. Design and sample size considerations for Phase IV studies is another active research area, in which a new class of hybrid designs has been proposed for scientific and regulatory purposes to detect rare adverse events.

College of Liberal Arts and Sciences
Department of Statistics
215 GLENBROOK ROAD, UNIT 4120
STORRS, CT 06269-4120
PHONE 860.486.3413
FAX 860.486.4113
www.stat.uconn.edu