Why do clinicians love 3+3? How do we help them de-love it?

How to properly model late onset toxicity?

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How to properly space doses?

How to properly design pediatric dose selection trials?
Neby Bekele

- Neby Bekele, Ph.D. is Vice President, Biostatistics at Gilead Sciences. Neby joined Gilead as a Sr. Director in January of 2011.

- Prior to Gilead, he was on the faculty at M. D. Anderson Cancer Center for 10 years.

- Neby’s research while at MD Anderson included applications of novel design and analysis methods to solve questions related to the design and analysis of clinical trial data. Other specific areas of interest include the application of Bayesian methods in clinical trials, adaptive designs, missing data problems and multiple testing procedures. He has 120+ collaborative/methodological peer-reviewed manuscripts and book chapters. His current interests lie in understanding the intersection between critical thinking skills, communication skills, and foundations of clinical trial design and practice.
Steven Goodman

- Steven Goodman, MD, MHS, PhD, is Associate Dean for Clinical and Translational Research and Professor of Medicine and of Epidemiology (HRP) at the Stanford University School of Medicine. He directs Stanford’s CTSA/Spectrum training programs in medical research methods and serves as chief of the Division of Epidemiology. He is co-founder and co-director of the Meta-Research Innovation Center at Stanford (METRICS), a group dedicated to examining and improving the reproducibility and efficiency of biomedical research. He has served on numerous Institute of Medicine committees since the mid 1990's, including committees on drug safety and sharing clinical trial data. He is currently the Vice-chair of the PCORI Methodology Committee (Patient Centered Outcomes Research Institute). He was awarded the 2016 Spinoza Chair in Medicine from the University of Amsterdam for his work on p-values, statistical inference and research reproducibility. He served on the ASA committee that drafted the 2016 ASA statement on P-values. From 1989-2011, Steve served on the faculties of the Johns Hopkins Schools of Medicine and Public Health, where he was a member for 20 years of the Johns Hopkins Cancer Center’s Division of Biostatistics and Bioinformatics, which he directed for 5 years and designed many Phase I trials.

Steve sang the National Anthem for the Golden State Warriors and SF Giants in 2017! Can I get tickets please?
Kevin Grimes

• Kevin Grimes is the Co-director of the SPARK Program in Translational Research and an Associate Professor in the Department of Chemical and Systems Biology at the Stanford University School of Medicine. Grimes received a Hartford Foundation Fellowship to study health economics at the Stanford Graduate School of Business and obtained an MBA. He was subsequently selected as a White House Fellow and assigned to the Department of Defense, where he served as Special Assistant to the Secretary. He spent fifteen years in industry, working in the medical device, life science consulting, and biotechnology sectors prior to returning to Stanford to co-direct SPARK. He has received the David Rytand Award for Excellence in Clinical Teaching and the Faculty Award for Excellence in Graduate Teaching.
Dr. Ray Liu is the Senior Director and Head of Advanced Analytics and Statistical Consultation group at Takeda Pharmaceutical Company, the largest pharmaceutical company in Asia with 236 years of history. Ray manages a group of 13 PhD level statisticians with responsibility to develop novel statistical methodology, and provide statistical consultation and project support for R&D.

Ray received his PhD degree from Columbia University. He published more than 30 statistical and scientific manuscripts and book chapters. He also edited two Springer books titled “Statistical Applications from Clinical Trials and Personalized Medicine to Finance and Business Analytics” and “Recent Trends in Pharmaceutical Statistics”. His current research interests are big data, text mining and joint analysis of high dimensional data.
Lei Nie

- Lei Nie is a lead mathematical statistician of the Division of Biometrics V in the Office of Biostatistics, CDER, FDA. Dr. Nie received his Ph.D. in Statistics from the University of Illinois at Chicago. Prior to coming to FDA at 2007, Lei was a faculty member in the University of Maryland Baltimore country from 2002-2005 and Georgetown University from 2005-2007.
Naitee Ting

- Naitee Ting is a Fellow of American Statistical Association (ASA). He is currently a Director in the Department of Biostatistics and Data Sciences at Boehringer-Ingelheim Pharmaceuticals Inc. (BI).

He just gave the short course yesterday! BIG thanks!!
Why do clinicians in FDA love 3+3? How do we help them de-love it? (SG)

How to properly model late onset toxicity? (NB)

How to use big data in drug development and dose selection? (RL)

How to design combination dose-finding trials in immunotherapies? (LN)

How to properly space doses? (NT)

How to properly design pediatric dose selection trials? (KG)