THE Flexner DISCOVERY LECTURE SERIES

Upcoming Discovery Lecture:

BRUCE GELB, M.D.

Gogel Family Professor and Director, Mindich Child Health and Developement Institute
Professor of Pediatrics and Genetics and Genomic Sciences,
Icahn School of Medicine at Mount Sinai

February 8, 2018
208 Light Hall / 4:00 P.M.

THE Flexner DISCOVERY LECTURE SERIES

ROGER J. LEWIS, M.D., Ph.D.

BAYESIAN ADAPTIVE PLATFORM CLINICAL TRIALS: A RESEARCH PARADIGM

JANUARY 4, 2018
4:00 P.M.
208 LIGHT HALL

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VANDERBILT CENTER FOR QUANTITATIVE SCIENCES

VANDERBILT UNIVERSITY MEDICAL CENTER

BAYESIAN ADAPTIVE PLATFORM CLINICAL TRIALS: A RESEARCH PARADIGM

The traditional approach to clinical trial design often requires assuming precise values for multiple unknown parameters, resulting in a trial design that is unlikely to perform well if one or more of the key parameters turn out to be quite different. During conduct, trial characteristics are often held fixed, even if incoming data suggest that one or more design assumptions were incorrect. This leads to an increased risk of a failed trial. In contrast, an adaptive clinical trial is designed to take advantage of partial, incoming data during the conduct of the trial, modifying key clinical trial characteristics according to prespecified rules, in order to avoid a failed or inconclusive trial, improve statistical efficacy, better treat patients within the trial, or achieve other scientific or ethical goals. The concept of an adaptive trial can be expanded to a platform trial, a clinical trial that is intended to evaluate multiple treatments or combinations of treatments, often for patients with any group of related diseases, and to continue beyond the evaluation of any particular treatment. Platform trials are ongoing or under development in a broad range of clinical areas, in the US and Europe and Asia, supported by government agencies, foundations, and industry. Design of an adaptive platform trial requires a qualitatively different research paradigm, with the focus shifted from the evaluation of each treatment to finding the best treatment for each disease. Multiple examples of Bayesian adaptive platform trials will be presented, both ongoing and currently under development, to illustrate the diversity and volume of research activity using this approach.

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Dr. Lewis received his MD and PhD degrees from Stanford University. He is a Professor at the David Geffen School of Medicine at UCLA and the Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. Dr. Lewis's expertise centers on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research; interim data analysis; data monitoring committees; and informed consent in emergency research. In 2009, Dr. Lewis was elected to membership in the National Academy of Medicine. He is a Past President of the Society for Academic Emergency Medicine (SAEM), currently a member of the Board of Directors for the Society for Clinical Trials, and the Senior Medical Scientist at Berry Consultants, LLC. Dr. Lewis has served as a grant reviewer for the Agency for Healthcare Research and Quality (AHRQ), the Canadian Institutes of Health Research (CIHR), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute of France, the National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI) and foundations. He has also served as the chair of data and safety monitoring boards (DSMB) for numerous federally-funded and industry-sponsored clinical trials, including international trials. He is a research methodology reviewer for JAMA and an editor of the JAMA series entitled "JAMA Guides to Statistics and Methods." He has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 240 original research publications, reviews, editorials, and chapters.