Addressing High Placebo Response in Clinical Trials: Doubly Randomized Delayed-Start Design to Increase Efficiency and Likelihood of Success

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Janssen R & D / Johnson & Johnson

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3:30-4:30pm, New PI 6th Floor Multipurpose Room (6602)
Light refreshments provided

Abstract

High placebo response rates have been a major source of difficulty in many neuroscience clinical trials and their effects have been difficult to overcome in developing new compounds. This difficulty has led to high failure rates in mood disorder trials, among others, even in trials with known effective drugs. To address this issue, this talk will offer insights into new enrichment design strategies, as well as approaches to reducing investigator and subject expectation bias. The concepts of enrichment, bias, and adaptation in clinical trials will be discussed. A newly proposed design will be introduced and its benefits examined relative to existing approaches in the literature.

Biographical Note

Dr. Pilar Lim is Senior Director of Clinical Biostatistics at Janssen R&D in Titusville, NJ. She is currently responsible for the Psychiatry programs and has been with Johnson & Johnson for 19+ years. She has over 30 years of research, consulting and teaching experience including 22 years of experience involving clinical development program strategy, clinical trial design, and analysis in the pharmaceutical industry in the disease areas of Immunology, Pain, Neurology, Cardiovascular and Metabolic Diseases, Anti-Infective Diseases, Women's Health, and Psychiatry. Dr. Lim has a Ph.D. degree in Statistics from the University of Pennsylvania. Prior to joining Johnson & Johnson, she taught at The Wharton School of the University of Pennsylvania and at Drexel University and also worked in the Immunology area at Centocor. Her research interests include multiplicity issues in statistical testing, non-inferiority analysis, and adaptive design

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[1] The PI Biostatistics Seminar Series is held on Tuesdays at New York State Psychiatric Institute. If you are interested in receiving regular announcements for our seminars in the future, or if you need further information, please contact Jina James (jamesji@nyspi.columbia.edu, (212) 543-5589).

methodology and implementation. Dr. Lim's collaborative experience with colleagues and medical researchers in various disciplines has led to over 20 publications in statistical and medical journals.

Dr. Justine Kent is a Senior Director at Janssen R&D within the Neuroscience Therapeutic Area. She is a graduate of New York University School of Medicine and completed her residency training in Psychiatry at Columbia University, where she served as chief resident in 1995. After completing a 3-year NIMH-sponsored Research Fellowship in Mood and Anxiety disorders at Columbia/NY State Psychiatric Institute, Dr. Kent was appointed to the research and teaching faculty of Columbia University's College of Physicians & Surgeons and served as the Associate Director of the Biological Studies Unit of NYSPI. In 2004 she joined the Department of Psychiatry at Morristown Memorial Hospital in Morristown, New Jersey as Associate Chair, where she directed a large child/adolescent and adult psychiatric outpatient service. In 2005, she joined Comprehensive NeuroScience, Inc., in White Plains, New York, where she advanced to Vice President and Senior Medical Director within the Clinical Trials/Clinical Drug Development Division. Dr. Kent has been at Janssen since 2008, where she is responsible for the development and execution of medical and scientific strategy for compounds in development for schizophrenia and mood disorders.