Statistical Initiatives at the US FDA Center for Drug Evaluation and Research

BIOSTATISTICS SEMINAR

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Statistics has historically played a pivotal role in the US Food and Drug Administration's oversight of drugs, and statistics continues to be central to many new FDA initiatives. Statistics at FDA entails the intersection of law, public health, and statistical methods and reasoning. US statutes and regulations provide the legal framework for the regulation of drugs and are based on sound scientific principles. Sound study design, analysis, and interpretation allow FDA to make decisions that have important public health implications. An example from a smoking cessation drug demonstrates how FDA was able to untangle the possible association with the drug with serious neuropsychiatric events. Recently, FDA has initiated a large effort exploring the potential uses of real-world evidence (RWE). RWE may leverage a variety of study designs from randomized studies, to external control studies, to full observational studies. RWE may offer evidence when traditional trials are not feasible or offer complementary evidence. Opportunities at FDA exist for statisticians with masters or doctorate degrees.

Thursday, February 10, 2022, 3:30-4:30 PM Eastern – Virtual using link and info below.

Link: https://unc.zoom.us/j/98412143955?pwd=a1p6c3hvZ28wSnk3dVVXQWl0dEpzdz09
Meeting ID: 984 1214 3955 Passcode: 0375501630