

Statistical Leadership in the Changing Landscape of Drug Development

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The Food and Drug Administration is posed to meet the demands of the changing landscape of drug development as evident by various commitments outlined in the 21st Century Cures Act and the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years 2018-2022, known as PDUFA VI. These commitments encompass a broad range of topics including real world evidence, complex innovative designs, patient-focused drug development, and model informed drug development. Statistical input, innovation, collaboration, and leadership will be essential to advancing drug development to meet the evolving needs of patients. I will provide an overview of the commitments and discuss the important role of the Office of Biostatistics in achieving the goals of the 21st Century Cures Act and PDUFA VI.