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Rajanikanth (Raj) Madabushi, Ph.D., is a Team Lead for Guidance and Policy Team in the Office of Clinical Pharmacology, Center for Drug Evaluation and Research, FDA, Silver Spring, MD. Dr. Madabushi received his Ph.D. degree in Pharmaceutical Sciences from Birla Institute of Technology and Sciences (BITS), Pilani, India. Following his Ph.D., he did a post-doctoral fellowship with Prof. Hartmut Derendorf at university of Florida, Gainesville. He joined the Pharmacometrics Group at FDA in 2005. As a pharmacometrics reviewer, he was predominantly involved in the application of quantitative clinical pharmacology approaches for regulatory decision making and addressing various drug development issues in the areas of Cardio-Renal, Hematology and Endocrinology drug products. In 2009, he became the Team Leader in the Division of Clinical Pharmacology I, specifically focusing the area of Cardiovascular, Renal and Hematology products. In 2016, Dr. Madabushi became the Team Lead for the newly formed Guidance and Policy Team in the Immediate Office of the Office of Clinical Pharmacology. Since then, he has been involved in the drug development, regulation, research and policy from a clinical pharmacology perspective.