

TITLE: FDA's Bayesian Guidance and the Future of Bayes in Regulatory Submissions**AUTHORS:** John Scott and James Travis - FDA, USA**PRESENTING AUTHORS BIO:**

John Scott is Director of the Division of Biostatistics and acting Deputy Director of the Office of Biostatistics and Pharmacovigilance in the FDA's Center for Biologics Evaluation and Research, which is responsible for regulating cellular, tissue and gene therapies, vaccines, and blood products. He is the CBER lead for 21st Century Cures and PDUFA efforts in Complex and Innovative Trial Design and has been heavily involved in a number of FDA's statistical policy and outreach projects, including the 2020 Guidance on Interacting with the FDA on Complex Innovative Trial Design, the ICH E9(R1) expert working group on estimands and sensitivity analyses, the 2026 draft Guidance on the Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products, and the ICH E20 expert working group on adaptive designs. Dr. Scott holds a Ph.D. in Biostatistics from the University of Pittsburgh, an A.M. in Mathematics from Washington University in St. Louis, and a B.A. in Liberal Arts from Sarah Lawrence College. He is a Fellow of the American Statistical Association and is a past Editor of the journal, Pharmaceutical Statistics.

James Travis is a master mathematical statistician in the Division of Biometrics II in the US FDA Center for Drug Evaluation and Research. He is the technical lead for the pediatric and maternal health statistical scientists and has been supporting pediatric drug development since joining the Pediatric Review Committee in 2017. He has worked extensively on applications in the complex and innovative trial design program and led the development of the FDA draft guidance "Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products". He received his PhD in Statistics from the University of Maryland, Baltimore County.