**Dr. Mark Rothmann** is the Director of the Division of Biometrics II, which reviews cardiology, nephrology, diabetes, lipids, obesity, and general endocrinology products. He earned his Ph. D. in Statistics at the University of Iowa in 1990. He then spent the next nine years as a professor at various universities before coming to the FDA in 1999. At the FDA, when he was a reviewer and team leader he was involved in the review on Oncology, Hematology, and Metabolism and Endocrinology products. Dr. Rothmann has published in many areas including non-inferiority trials, missing data and subgroup analysis. He is the lead author of the book “Design and Analysis of Non-Inferiority Trials.” He has additionally presented externally for the FDA on Bayesian Analysis in Pediatric Settings, Master Protocols, Bayesian Hierarchical Models and Shrinkage Estimation and Surrogate Endpoints. He currently leads three Office of Biostatistics (OB) Working Groups and Committees in Bayesian Analysis, Drug Trials Snapshots and Pediatric Studies and has served on many other working groups and committees.

As the office lead on pediatric studies and chair of the OB committee on pediatric studies, Dr. Rothmann has worked with members of the Division of Pediatric and Maternal Health and participated on projects involving pediatric therapeutic areas. As a founding member of the American Statistical Association Pediatric Studies Working Group, he works with statisticians and clinicians in industry and academia to advance pediatric drug development and the education on pediatric drug development. For his work in Pediatrics, he has received 5 FDA/CDER awards.

Dr. Rothmann has done much work in the related areas of Subgroup Analysis, Drug Trials Snapshots (DTS), Heterogeneous Treatment Effects, Diversity and Personalized Medicine. In these collective areas he has published five papers plus an FDA impact story, he has given 29 presentations or served on panels, and he has served on eight related committees or working groups. For his work in these collective areas, he has earned 4 FDA/CDER awards. In 2021 he has organized, presented, or served on a panel with RADM Richardae Araojo in three sessions on Diversity, Equity, and Inclusion in Clinical Trials.