International Alliance for Bioloaical Standardization

The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Jeff Roberts joined Merck Research Laboratories (MRL) in November 2021 as Associate Vice President, Vaccine Clinical Development. In this role, he is responsible for clinical development of candidate and licensed vaccines for a variety of disease targets.

Prior to joining MRL, Jeff was Associate Director for Scientific Affairs in the Office of Vaccines Research and Review at the US FDA. His focus included emerging disease threats/medical countermeasures and use of digital health tools, alternative clinical trial designs, and real world evidence to support product development/licensure. He also led discussions/coordination on vaccine development with other regulatory authorities. Prior to that, and for most of his 14 years at the FDA, Jeff served as Clinical Branch Chief in the Division of Vaccines and Related Product Applications (DVRPA), where he managed the clinical review activities for development programs and licensure applications for multiple products, including vaccines, allergenic products, phage therapy, and live biotherapeutics. In addition to managing the clinical review group, Jeff led several efforts to advance the regulatory science on topics like maternal immunization, human challenge models, and the use of biomarkers to enable vaccine development.

Jeff received his MD degree from the University of Alabama School of Medicine. He trained in OB/GYN at the University of Colorado. He then spent several years at the National Cancer Institute at NIH doing basic research and animal modeling with HPV prior to moving to the FDA.