Keynote Speaker

Ram C. Tiwari, Ph.D., Head of Statistical Methodology at BMS since February 1, 2021. His prior services include serving at FDA, NCI/NIH and in academia. He received his MS and PhD degrees from Florida State University in Mathematical Statistics. He is a Fellow of the *American Statistical Association* and a past President of the *International Indian Statistical Association*. Dr. Tiwari has over 200 publications on statistical methods, and a newly authored book on "Signal Detection for Medical Scientists: Likelihood Ratio Test-based Methodology" published by Francis &Taylor.

Time: September 14 (Tuesday): 9:00-10:00AM (Eastern Time)
Host: Margaret Gamalo, Ph.D., Senior Director - Biostatistics, Pfizer Innovative Health

Title: Leveraging External Evidence for Augmenting a Single-Arm Study

Abstract: There is a wide variety of study designs that involve the leveraging of external data. These external data can be leveraged to augment a single-arm study, or construct or augment either the control arm or the treatment arm (or both) of a comparative clinical study, and they may come from a single source or from multiple sources. In this talk, I will use illustrative examples to present novel propensity-score based methods for leveraging external data to augment a single-arm study or to augment the control arm of a randomized controlled trial (RCT). These methods can be utilized for medical drug/device development.