

**TITLE: Prediction of Overall Survival (OS) from Disease Progression Dynamics in Metastatic Cancer Trials**

**AUTHOR:** Satrajit Roychoudhury, *Pfizer Inc.*

**ABSTRACT:**

Progression-free survival (PFS) and overall survival (OS) are commonly used primary and key secondary endpoints in the metastatic cancer trials. Although in recent years many regulatory approvals are based on PFS improvements, OS remains gold standard to access patient benefit. However, powering a trial for OS benefit can be challenging due to several factors including longer duration, patients crossing over after progression, or lost to follow-up. Moreover, OS data is often not mature enough for proper statistical inference at the time of the primary analysis of PFS. Therefore, it is important to i) characterize the risk of mortality ii) accurately predict the timing of matured OS analysis using all available information. We propose a joint modeling approach along with Bayesian model averaging by considering granular components of disease progression to predict mortality of individual patients. The model accounts for multiple sources of heterogeneities along with the baseline risk factors. Extensive simulations are performed to under different scenarios to evaluate the model performance. Finally, the practical utility of the study is illustrated using a real-life case study.

**AUTHOR BIO:**

Dr. Satrajit Roychoudhury is an Executive Director and Head of the Statistical Research and Innovation group in Pfizer Inc. He has 17 years of extensive experience in working with different phases of clinical trials for drug and vaccine. His research interest includes survival analysis, use of model-based approaches and Bayesian methods in clinical trials. He served as the industry co-chair for ASA Biopharmaceutical Section Regulatory-Industry Workshop in 2018 and co-chair for DIA/FDA Biostatistics Industry and Regulator Forum in 2023. Satrajit is an elected Fellow of the American Statistical Association and recipient of Royal Statistical Society(RSS)/Statisticians in the Pharmaceutical Industry (PSI) Statistical Excellence in the Pharmaceutical Industry Award in 2023 and Young Statistical Scientist Award from the International Indian Statistical Association in 2019. He authored Statistical Approaches in Oncology Clinical Development and co-authored several book chapters on statistical methods in drug development.