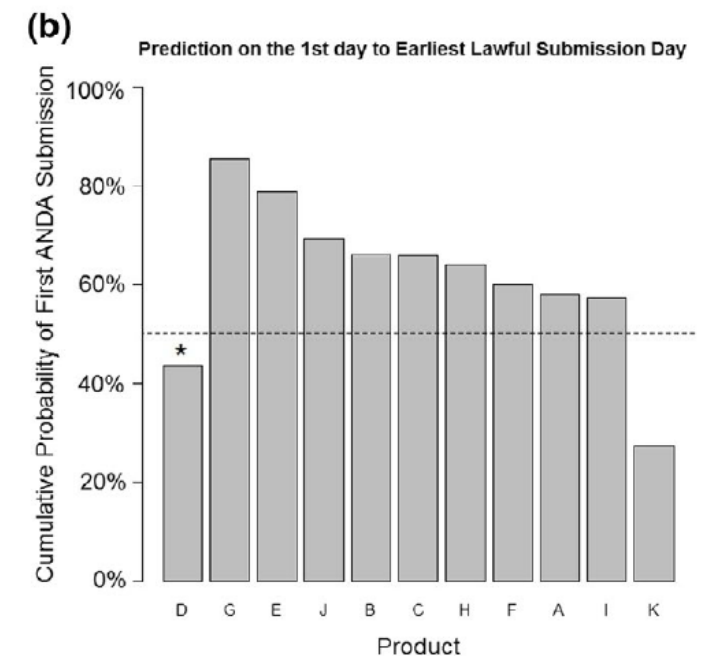
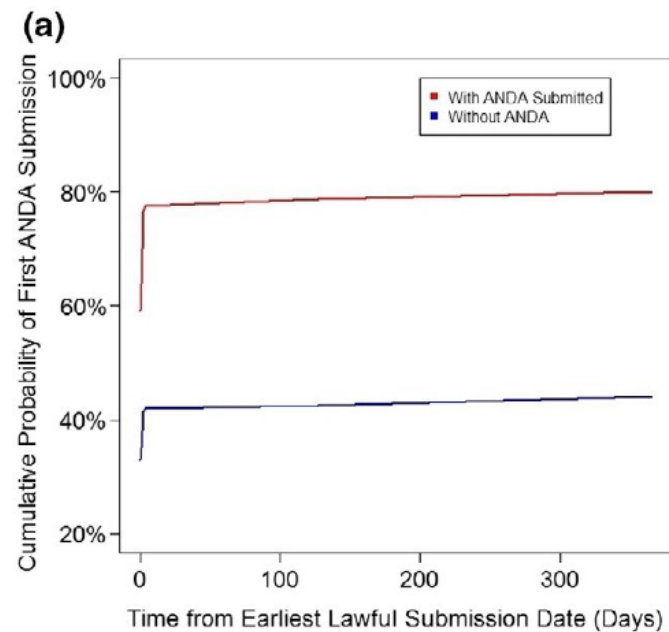
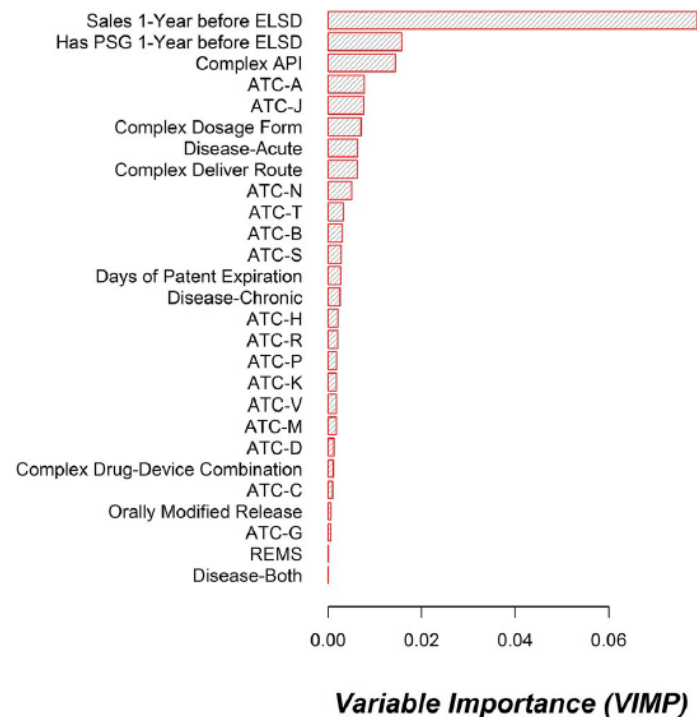


Predictive Analysis of First Abbreviated New Drug Application Submission for New Chemical Entities Based on Machine Learning Methodology

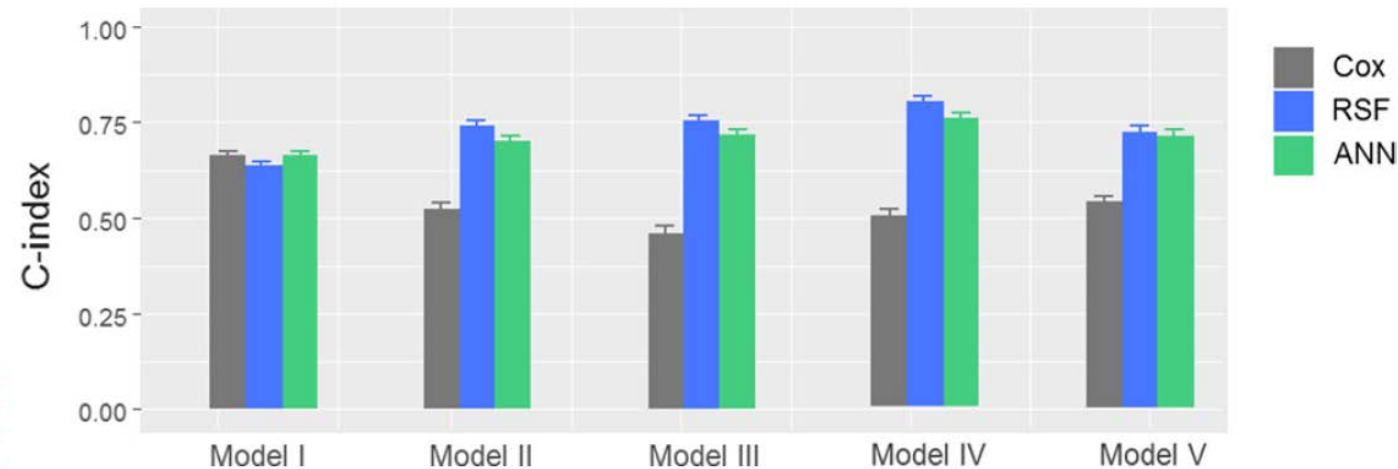
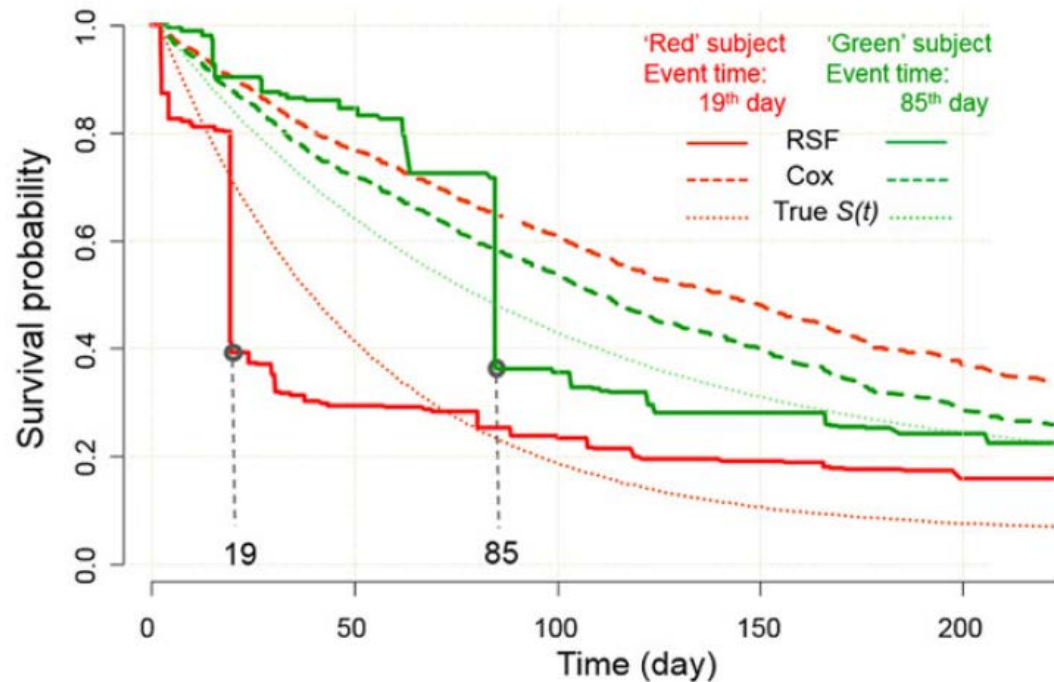
- Random Survival Forest (RSF) ML method is employed to forecast the time to first ANDA submission, referencing a new chemical entities (NCE) drug product
- RSF is superior in predictive performance comparing to conventional time-to-event methodology
- Variable importance of predictors (e.g., drug product, regulatory and pharmacoeconomic information variables) is assessed



Big Data Toolsets to Pharmacometrics: Application of Machine Learning for Time-to-Event Analysis



- Big Data tools (machine learning, ML) are applied to address pharmacometric problems
- The predictive performance of ML methods is superior compared to the Cox regression model under various simulated scenarios
- ML methods demonstrate less sensitivity to data sizes and censoring rates



Equivalence Testing of Complex Particle Size Distribution (PSD) Profiles Based on Earth Mover's Distance (EMD)

- EMD approach is employed to compare complex PSD profiles for equivalence assessment
- The developed approach is both effective and sensitive to pass equivalent products and reject inequivalent products in cases of multimodal PSD

