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Biased borrowing or borrowing bias? Leveraging Bayesian borrowing and quantitative bias analysis for robust comparative effectiveness insights

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Please provide a brief biography for the Presenting author(s)
Grace is Director of Real-World Evidence at Cytel providing statistical consulting and guiding project strategy for the application of advanced analytics to clinical and RWE generation. She also develops statistical communications and training for non-statisticians. Examples of her peer-reviewed publications include work on COVID-19, synthetic/external control arm comparative effectiveness analysis, quantitative bias analysis, Bayesian borrowing and other methods for comparative studies for both pharmaceutical research and HTA/regulatory submissions.

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This presentation is on the methodology in a study aimed to evaluate the comparative effectiveness of nivolumab versus nivolumab + ipilimumab for overall survival (OS) and progression-free survival (PFS) in patients with metastatic colorectal cancer using non-randomized trial data. A Bayesian borrowing framework was used to integrate evidence from a third non-randomised arm, enhancing statistical power while accounting for differences between data sources. To assess the robustness of the findings, we implemented comprehensive quantitative bias analysis (QBA) addressing key potential biases, including misclassification of microsatellite instability-high (MSI-H) status, unmeasured confounding, missing data, and target cohort differences introduced by Bayesian borrowing.

The study design incorporated sensitivity analyses for each source of bias, leveraging both evidence from the literature and expert elicitation to determine the set of confounders and other study assumptions. QBA highlighted scenarios under which effect estimates remained robust or became sensitive to specific biases, offering nuanced insights into data limitations and model assumptions.

This study also serves as a practical demonstration of combining Bayesian borrowing with QBA, especially in oncology where robust comparative effectiveness research is crucial for decision-making. Practical takeaways include strategies for handling many bias scenarios. These findings can inform the design of rigorous studies in similar contexts, demonstrating practical applicability of real-world evidence in precision oncology.