

FDA Sentinel Innovation Center

- **Safety evaluation with high dimensional data:**

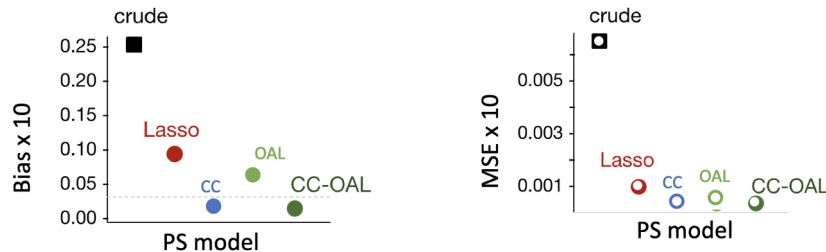
Wyss et al. (2024), AJE, Targeted Learning with an Undersmoothed Lasso Propensity Score Model for Large Scale Covariate Adjustment in Healthcare Database Studies.

- **Subset calibration/two-stage designs:**

-Ongoing project evaluating methods such as the two-stage design TMLE for study designs that involve a subset of subjects with carefully curated confounders and or outcomes, and a remaining set of subjects.

-This is a common type of design to obtain desired causal identification from RWD while still gaining efficiency from the less curated data set.

Plasmode study results



Collaborative control greatly reduced bias and improved MSE

- Less regularization captured more relevant confounder information in PS

These projects involve multi-author working groups with FDA/Pharma/Academics/Kaiser Permanente.

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