

CardioOracle: Predicting Cardiovascular Trial Outcomes Using Bayesian Historical Borrowing and Design Feature Analysis

Can we predict the probability of a cardiovascular clinical trial meeting a primary endpoint, from historical trial characteristics and design features? Our tool was trained on an 784 labelled Phase 2/3 and Phase 3 Cardiovascular trials from the ClinicalTrials.gov AACT database,, with outcomes assigned via automated p-value extraction, confidence interval heuristics, and manual landmark curation. CardioOracle combines Bayesian historical borrowing from similar completed trials, uses conditional power analysis using endpoint-specific formulas, and L2-regularised logistic meta-regression on 18 design features in a weighted ensemble. The model achieved AUC of 0.787 (95% CI 0.75 to 0.82, Brier score 0.169) in-sample and 0.745 (Brier 0.196) on 133 temporally held-out post-2020 trials. Leave-one-out analysis confirmed the directional accuracy for major outcomes trials, such as DELIVER, FINEARTS-HF, and EMPACT-MI. Historical trial data contains quantitatively exploitable signals concerning cardiovascular trial success that can meaningfully inform future prospective design decisions. Predictions are currently limited by observational training and data and cannot currently replace prospective trial monitoring or adaptive interim analyses

References

1. Aggregate Analysis of ClinicalTrials.gov (AACT) / ClinicalTrials.gov registry, U.S. National Library of Medicine. Available from: <https://clinicaltrials.gov>