



ML-BASED PREDICTION OF CLINICAL TRIAL SUCCESS OR FAILURE

INTRODUCTION

- Machine learning (ML) tools are used with growing success across industries to improve decision-making. Businesses that have access to large volumes of high-quality data are increasingly turning to ML to perform tasks where humans can not take decisions. Recently ML approaches have been widely benefited in various fields such as predicting risk or fail, fraud detection, imaging classification, designing molecule, automating processes, understanding customer behavior including drug discovery development.
- Drug development is a time-consuming process and expensive (costs about \$2168 million per approved drug in research and development) but faces failure rates that often exceed 90%, a model that could predict the outcomes of clinical research phases would be particularly valuable. Few ML-based studies are suggested to mine clinical trials data in order to predict the likelihood of clinical trial success and regulatory approval for drug candidates.

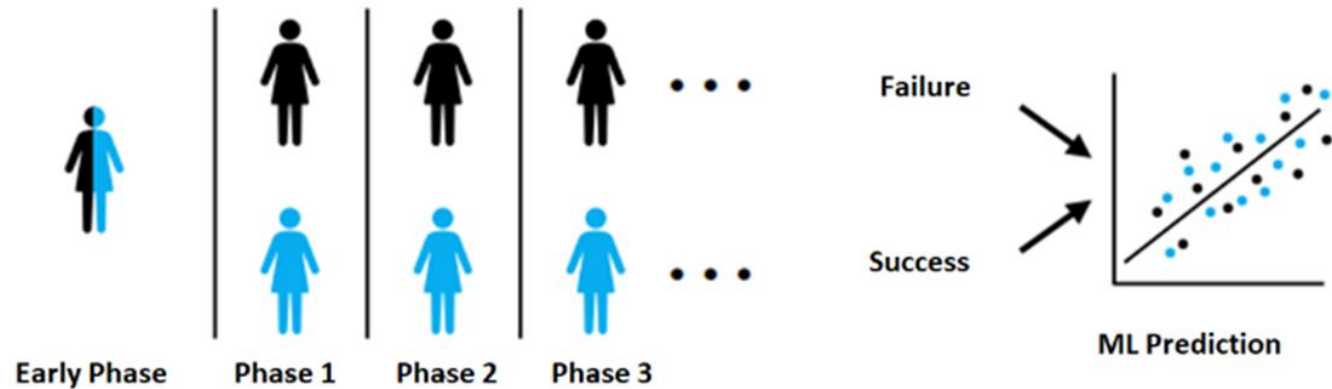
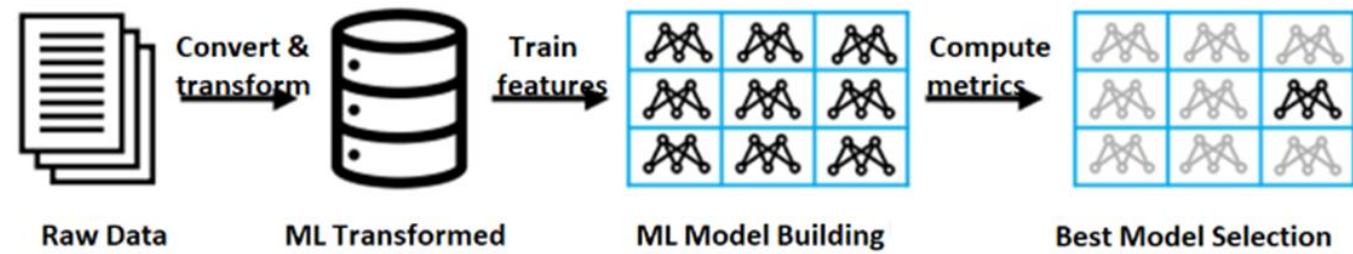
PROBLEM STATEMENT

- Current approaches for the design of clinical trial study as well as the prediction of clinical trial success or failure is a challenging task. Also, the traditional approaches require huge cost and time (about 10-15 years) as well as the final drug approval into the market is about 10%. Our pipeline focuses on the development of machine learning model based on the existing clinical trials data available for the disease such as demographics, drug, treatment regimen, inclusion and exclusion criteria, and primary and secondary outcomes. This pipeline focuses on the prediction of undergoing clinical trials as success or failure related to type 2 diabetes based on the trained data from the drug intervention, completed clinical trials including the phase IV approved drugs which has results and predict on on-going early phase, phase I/II/III trials.

CHALLENGES

- Integration of multiple clinical trial registry data analysis.
- Normalizing medical terminology.
- Handling heterogeneous samples data like inclusion and exclusion criteria.
- Results with primary and secondary outcome measures.
- Feature selection plays a major role in model prediction.
- Individual patient level data is not publicly accessible.

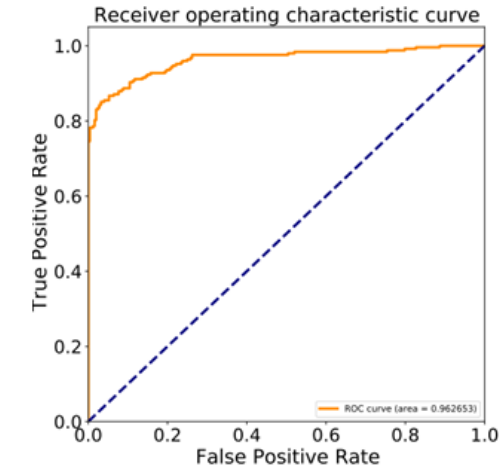
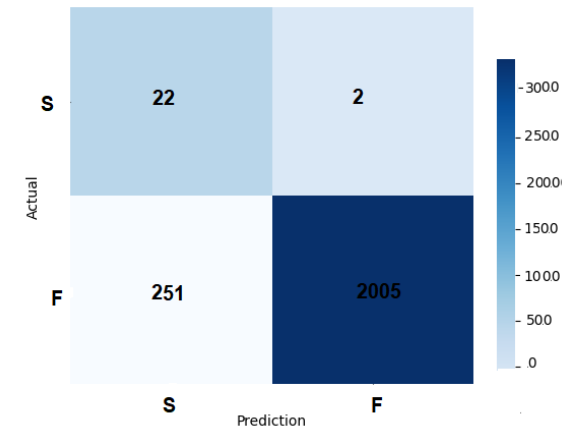
OUR APPROACH



RESULTS

A. Performance Metrics, Confusion Matrix, ROC Plot for Best Model

Classifier	Specificity	Sensitivity	Accuracy
LR	0.73	0.77	0.75
NB	0.73	0.78	0.76
SVM	0.77	0.81	0.79
RF	0.79	0.81	0.80
DT	0.76	0.79	0.78
GBM	0.8	0.82	0.81
MLP	0.81	0.85	0.83
AB	0.78	0.79	0.78
BB	0.79	0.81	0.8
EE	0.89	0.92	0.89
BRF	0.84	0.88	0.86
RB	0.84	0.86	0.85



IMPACT

- ML predicted clinical trial as success or failure for type 2 diabetes.
- This tool will be beneficial for patients and helps in huge cost reduction, easy for drug regulatory approval, as well as predict the risk for failure so that the time and expenditure is minimal.
- One primary reason as to why the proposed pipeline is potential and useful – using heterogeneous clinical trial data analysis to predict the clinical trial success or failure. Also, further use the model predicted features to design the future clinical trial to be successful.

WHY 3BIGS?

- 3BIGS enable our customers to design novel clinical trial design as well as predict the trial as success or failure for a specific disease using machine learning. By assiduous reduction of the inherent noise in the clinical trials, 3BIGS pipeline has alleviated the challenges of utilization of drug, treatment regimen, inclusion and exclusion criteria, and primary and secondary outcome by transforming the data into binarized features and reduce the redundant or inherent noise using feature reduction technique and improve the accuracy in the outcome of the trials. We also have high-end servers at our end which can additionally reduce the time required for these analyses.
- 3BIGS solution offers an affluent scheme of machine learning (ML) algorithms and statistical tools to enable the pharmaceutical companies, sponsors or funding agencies, and clinicians to give better inference and faster insights from clinical trial data. Vantage 3BIGS expertness in designing a better clinical trial as well as data analysis techniques to predict success or failure of the drug for disease. Meliorate your R&D efforts today and use our tested and validated models or build models of your own with much ease using our ML trained data.