

Utilizing Neural Network to Identify CDER Manufacturing Sites with Non-compliant Good Manufacturing Practice(GMP) Inspection Outcomes

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Objectives

The deep learning approach, neural network is used to predict whether a site in CDER manufacturing catalog will have non-compliant GMP inspection outcome

- 1 Illustrate the algorithm of neural network with hidden layers
- 2 Implement neural networks(NN) of different structures and logistic regression(LR) model with 5-fold cross validation, a machine learning data partition technique
- 3 Evaluate models' performance with true positives, Matthew's correlation coefficient(MCC), Cohen's Kappa.

Introduction

Deep neural network, inspired by the biological neural systems, today is a widely used framework of processing information in artificial intelligence and business risk management. CDER|OPQ|OS assures that quality medicine are available through data analysis, signal detection and surveillance activities. With FY2018 CDER manufacturing data and FY2007-2017 ORA inspection outcomes, Neural network is leveraged to identify non-compliant CDER manufacturing sites based on GMP inspection conducted by ORA.

Neural Network Paradigm

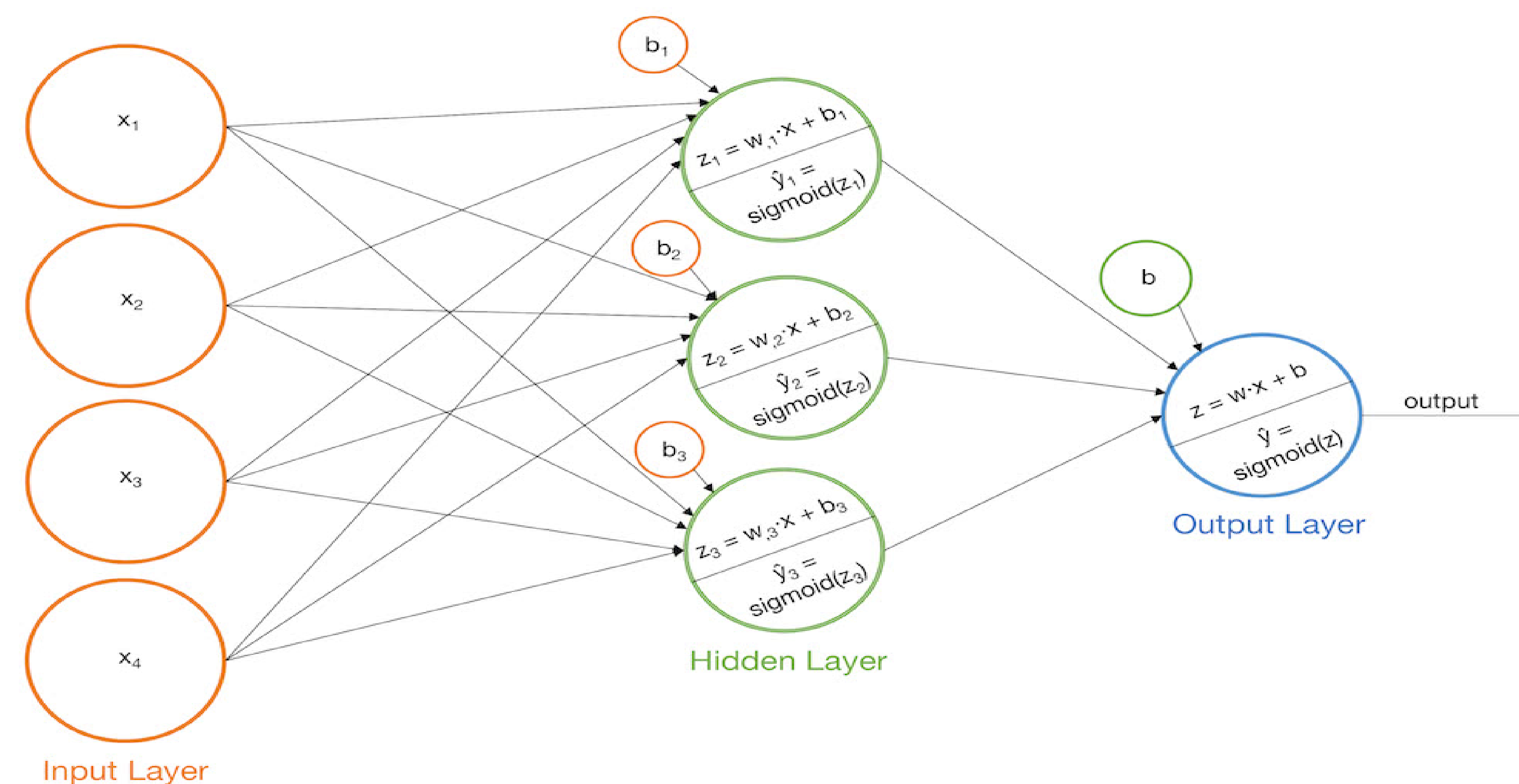


Figure 1: Scheme of Neural Network with One Hidden Layer[1]

Models

Neural Network Structures

Hidden layer=1, neurons=5
 Hidden layers=2, neurons=7

Target Outcome

Initial Inspection Outcome is 'Official Action Indicated(OAI)'

Features

Last Inspection Outcome
 Inspection Basis
 Profile Class Code Type
 Hazard Signal
 Quantity of Inspections
 Years since Last GMP Inspection

Results

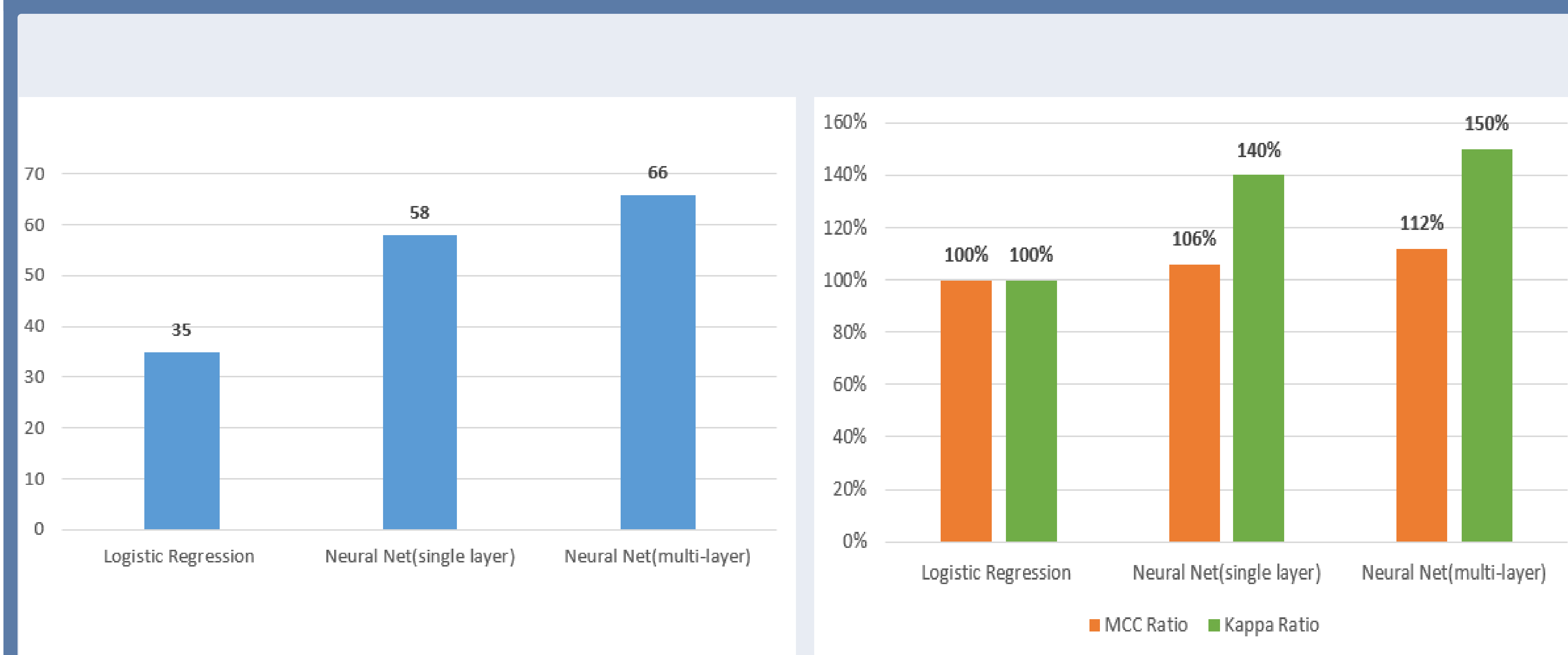


Figure 2: Total True Positives

Figure 3: Ratio of NN to LR in avg MCC and avg Kappa

Discussions

Neural Networks have more capability in identification of sites with OAI cases over logistic regression in this study. Further work would involve feature engineering to achieve improvement in prediction potentiality.

Reference

[1] Introduction to Neural Networks <https://www.gormanalysis.com/blog/introduction-to-neural-networks/>

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