Predicting Future ICER Value Assessments: A Neural Network Approach

Saber J[1], Kennedy L[1], Haynie S[1], Irwin K[1].
[1]Innopiphany LLC, Irvine, CA, USA

Contact: Junko.Saber@Innopiphany.com

STUDY OBJECTIVE

o **Situation:** The Institute for Clinical and Economic Review (ICER) is a non-profit price watch-dog focusing on the cost-effectiveness and comparative clinical benefit of new and upcoming therapies.

o **Challenge:** ICER assessments are highly disruptive to manufacturers' operations and pose commercial and reputational risk to a company if they receive an unfavorable assessment.

o **Question:** This study sought to determine whether Innopiphany's predictive model can accurately determine which therapies are at risk of ICER assessment with publicly available data, to better prepare companies for an assessment.

METHODOLOGY

Data

Analysis Methods

Data for the dataset was compiled from three major sources:
1. FDA Drug Approval Data
2. ICER Assessment History Data (2016-May 2022)
3. Indication-Specific Data (i.e.. Prevalence)

Drugs were flagged as one of three options:
1. ICER Intervention
2. ICER Comparator
3. Not Assessed

Over 85,000 data points were compiled to train the models.

A **Neural Network** and **K-Means Clustering** dual approach was used to develop a predictive model that would predict how the therapies would be classified into the three options (Intervention / Comparator / None). Random Forest was also tested and eliminated due to poor performance.

SMOTE was used to account for differences in sample size between the three groups.

RESULTS

Table 1: Neural Network Model Results

Model	Type of Record	Record Count	% Correct**	% Highly Likely to Be Intervention or Comparator
100% Model	Original and SMOTE	2,545	95.9%	15%
80% Training Model	Original and SMOTE	2,011	98.8%	4%
20% Validation Sample	Original only	140	72.1%	26%
All Original Records Using 100% Model	Original only*	692	86.4%	15%

*   Includes only NDAs, not generics, sNDAs or BLAs
** Identified correctly as an ICER intervention/comparator, or not assessed (None)

Table 2: K-Means Clustering Model Results

Cluster	Count Comparator	Count Intervention	Count Not Assessed
1	8	1	46
2	13	4	290
3	0	8	21
4	1	22	167
5	4	6	101

KEY: Cluster 1 – Comparator, Cluster 2 – Comparator, Cluster 3 - Intervention, Cluster 4 - Intervention, Cluster 5 - None (Neither intervention or comparator)

LIMITATIONS

Novel Indication: Due to FDA approval data structure, indication is not listed except for select FDA approval types. This analysis is limited to the original indication and excludes supplemental indications, restricting the number of linkable ICER assessments. Additional effort is underway to include supplemental indications and newer data for further model refinement

Small Molecule: These results are limited to small molecules only. Additional efforts are underway to develop a model for biologics as well.

DISCUSSION

Table 1: The results of the model testing via the Neural Network approach demonstrate 86% predictive accuracy in classifying a drug as either an intervention, comparator, or neither, and 72% prediction accuracy after 80/20 validation testing.

Table 2: The majority of ICER interventions are in Clusters 3 and 4. Most are in Cluster 4, with 53% (22) in that cluster. The next highest concentration of ICER interventions are in Cluster 3, with 19% of all ICER assessed (8) in Cluster 3. Cluster 3 also has the highest concentration of ICER assessed products, with 27% (8) of the 29 Cluster 3 products having been ICER assessed. Comparators are concentrated in Clusters 1 and 2, with 14 in Cluster 2 and 8 in Cluster 1. These clusters represent 81% of all Comparator products.

CONCLUSIONS

Innopiphany integrated regulatory, ICER, and disease-specific data and utilized machine learning techniques, including Neural Network and K-means clustering, to model and predict the likelihood of a small molecule's inclusion in an ICER assessment. The model can be used to determine the probability that a product will be included as either a comparator or intervention of interest with high predictive accuracy. The model is validated to over 72% accuracy on products excluded from model development, with overall model achieving 96% accuracy.

Impact: Given ICER's rapid timelines, effectively responding to an ICER assessment requires cross-functional planning, alignment and collaboration. An early warning on likelihood of assessment can help companies allocate the appropriate personnel to proactively and more effectively engage with ICER.

Next Steps: Future analytics steps will involve continuing to evaluate model performance with new FDA approvals and ICER assessments and incorporating additional predictors as discussed in the limitations section.

ICER = Institute for Clinical and Economic Review,
SMOTE = Synthetic Minority Oversampling Technique