

BENEFIT RISK ASSESSMENT



Industry Need

Decision-making with regard to the benefits and risks of drugs is fundamental and is often complex for both experimental and marketed drugs. Current benefit risk analysis approaches are human effort intensive, taking up about a third of overall safety and medical affairs operations efforts. With the advancement in data analysis techniques using machine learning (ML), artificial intelligence (AI) and natural language processing (NLP), there is an opportunity to gain efficiencies while successfully and continuously monitoring the benefit risk profile of medicines.



Key Solution Attributes/Tenets

Infosys is working towards automating the Benefit Risk Assessment (BRA) process using frameworks such as PROTECT <http://protectbenefitrisk.eu/> to provide an integrated view across the 5 stages of benefit risk assessment roadmap.

Evidence gathering and data preparation: Identify data sources; extract evidence relevant to the BRA using NLP, Classification, Deep Learning like SVM, Neural Networks, etc.

Exploration: Validate results with assumptions and uncertainties; consider impact or added value of risk minimization measures



Planning: Understand critical issues related to a particular BRA, including the purpose and context of the assessment



Analysis: Data evaluation, data analysis using frameworks and algorithms such as BRAT, ProACT-URL, ITC, MCDA, SMAA, etc., that are relevant to BRA; quantifying the magnitudes of benefits and risks and applying weightages. Visualize the analysis outcome through industry standard tools such as Tableau/ R-Shiny or create complex visualizations using Javascript libraries



Conclusion and Dissemination: Communicate results, gain consensus, provide an audit trail of the assessment process



Outcomes

The platform helps biostatisticians, epidemiologists, patient safety personnel and regulatory stakeholders to comprehensively evaluate and monitor benefit risk profile of their drug through clinical development and post-marketing stages; it also helps in assessing the benefit risk profile of the drugs vis-à-vis those from competitors.