AI-enabled decision making in drug safety

Oscar Courbit, Hermine Trané
Faculty Advisor: Alex Jacquillat
Takeda Sponsors: Saurabh Awasthi, Dona M. Ely, Maria Camila Mareno

Problem Statement
We turned an exploratory project on how to use AI to guide pharmacovigilance into an operational, interactive app that detects adverse events during clinical trials.

Data

- **$77-$138 Billion** annual cost of Adverse Drug Reactions in the US
- **37187** Patients
- **90k+** Reports of adverse drug reactions
- **250+** Features for each patient
- **100+** Countries
- **0.5%** Proportion of patients with the adverse event studied
- **3 Drug-Event Combinations**

Key Results

- **Model 4 AUC Outperforms across DEC**

- **Causal drugs findings**
  - taking enoxaparin (blood thinner) increases on average by 28% the risk of cardiac disorder (between 6 and 59%)
  - taking ondansetron hydrochloride (anti-emetic) increases on average by 12% the risk of cardiac disorder (between 0 and 25%)

You can find all the results in our fully automated WebApp!

Methodology

- **CHALLENGE**
  - Multimodal & Unstructured Data
  - Many Concomitant Factors
  - High Class Imbalance
  - Need for Interpretability

- **SOLUTION**
  - Natural Language Processing
  - Graph Concomitant Product Analysis
  - Regress and Compare for Causal Effect of Drugs
  - Ensemble Learning and Under sampling
  - Interpretable Trees

- **IMPACT**
  - Extracted 5000+ Drugs
  - Selected Representative Drugs
  - Identified 45+ Causal Drugs
  - Increased AUC from 0.50 to 0.89
  - Found 5 Highly Significant Features
  - At 95% on Performance

Performance

Decision Making Framework

- **R&D** Clinical Trial Marketing
- **AUC**
- **Do we continue developing this drug?**
  - Predict adverse event based on demographics data
- **Is there a causal relationship between the initiation of the Takeda product and the adverse event?**
  - Analyze influence from other drugs
- **Do we market this drug?**
  - Add dosage information to prediction
- **What do we add to the label?**
  - Add initial light reaction

Impact

- **Fully automated WebApp to support efficient decision-making**

- **1) Empowering Patient Confidence**
  - Refined drug labels empower patients

- **2) Vigilance in Vulnerability**
  - Swift identification of susceptible patient subgroups

- **3) Preserving Patient Well-being**
  - Thousands of patients spared from adverse reactions

- **4) Global Influence, Individual Lives**
  - Impact on millions through Takeda’s reach

- **5) Informed Risk Reduction**
  - Expert insight into dangerous drug combinations

- **6) Hidden Beneath the Surface**
  - Unveiling and preventing potential adverse events

- **7) Revolutionizing Generalizations**
  - Bridging clinical trials to real-world patient benefit

- **8) Empowerment Through Adaptation**
  - Dynamic research redirection for ongoing patient safety

- **Massive Patient Impact**: 31 million patients across 100+ countries trust Drug 2 yearly; our safety efforts enhance their lives.
- **Preventing Hidden Risks**: ~30,000 adverse reactions known, countless more prevented by Takeda’s vigilance, shielding patients from harm