AI-enabled decision making in drug safety


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

Pioneering patient safety: Leveraging AI to predict adverse drug outcomes

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

$77-$138 Billion
annual cost of Adverse Drug Reactions in the US

- How can we **assess our drug's actual impact** compared to other drugs that a patient is taking?
- What are the **key population subgroups** that are at **higher risk of developing a given adverse event**?
- How can we predict **whether a patient is going to develop this adverse event**?

Data

Reports from Pharmacovigilance Meetings | Demographic Information | Dosage Information | Historical Conditions

3 Drug-Event Combinations	**100+** Countries	**37187** Patients
250+ Features for each patient	**0.5%** Proportion of patients with the adverse event studied	**90k+** Reports of adverse drug reactions

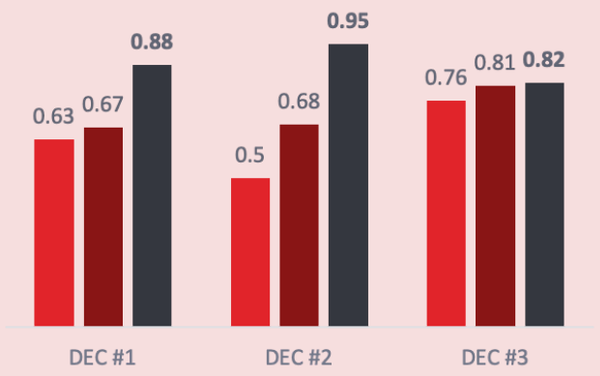
The HEVER group, a global consortium of pharmaceutical R&D heads, shortlisted our project to revolutionize the industry with AI

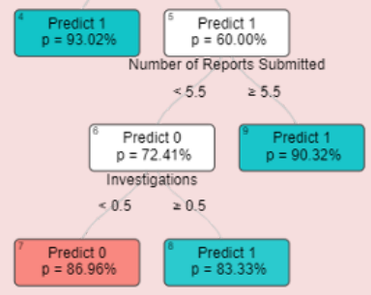
Methodology

	CHALLENGE	SOLUTION "fancy" models used	IMPACT
1)	Multimodal & Unstructured Data	• Natural Language Processing • Graph Concomitant Product Analysis	➢ Extracted 5000+ Drugs ➢ Selected Representative Drugs
2)	Many Concomitant Factors	• Regress and Compare for Causal Effect of Drugs	➢ Identified 45+ Causal Drugs
3)	High Class Imbalance	• Ensemble Learning and Undersampling	➢ Increased AUC from 0.50 to 0.95
4)	Need for Interpretability	• Interpretable Trees • Robustness of Feature Significance	➢ Found 5 Highly Significant Features ➢ At No Cost on Performance

Key Results

Model 4 AUC Outperforms across DEC





Tree to interpret model decisions

eg. Patients who submitted **more than 6 previous events** and had an **average dose > 126.6mg** are **more likely to face a cardiac disorder**

Causal drugs findings

- taking **enoxaparin** (blood thinner) increases on average by **28% the risk of cardiac disorder** (between 6 and 50%)
- taking **ondansetron hydrochloride** (anti-vomitting) 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!

Performance

DEC #1	Model 2	Model 3	Model 4
TPR	0.75	0.65	**1.00**
FPR	**0.04**	0.16	0.28

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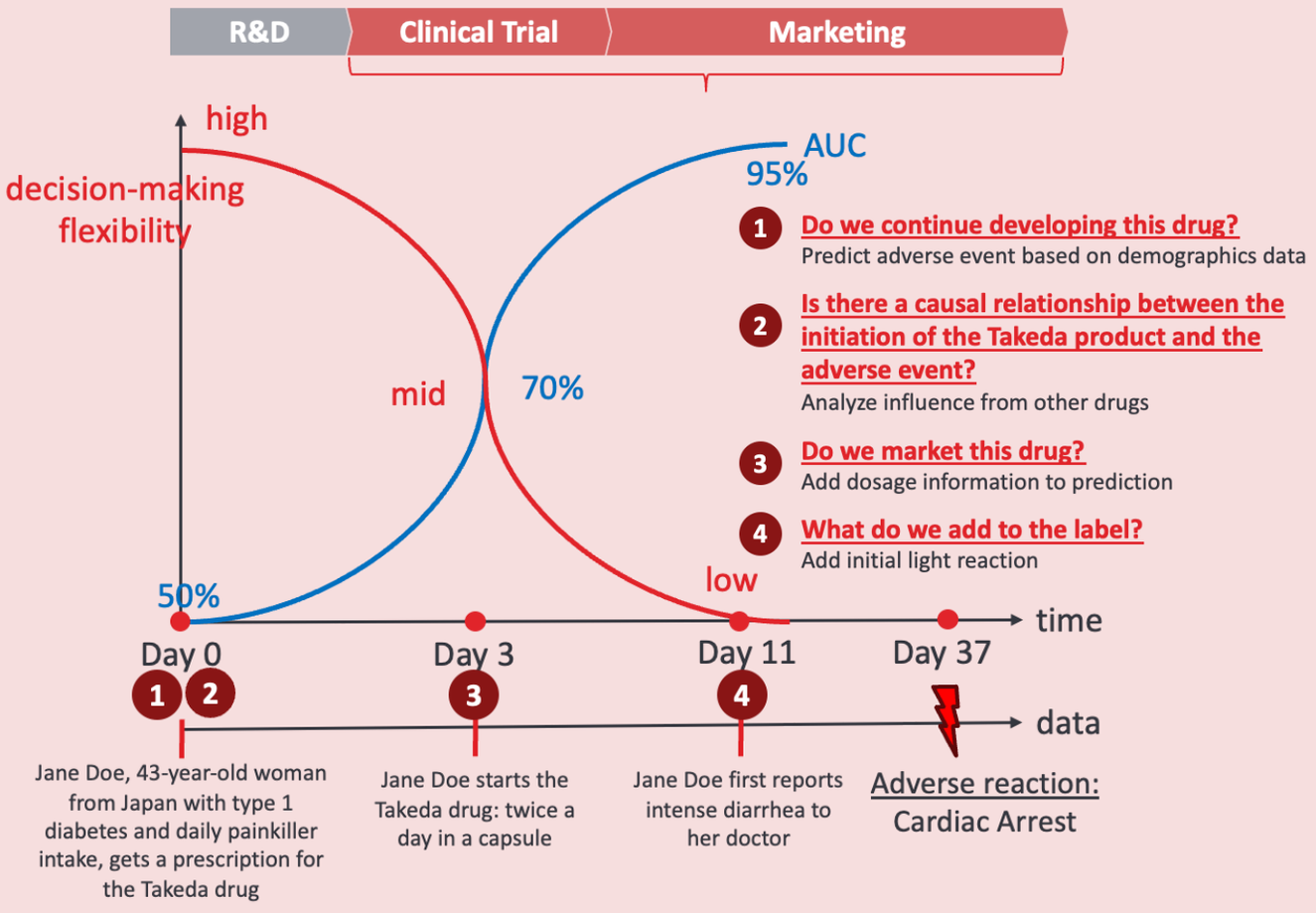
	Ensemble Model AUC	Tree Model AUC	Tree Model Representativeness
DEC #1	0.88	**0.91**	87%
DEC #2	**0.95**	0.86	94%
DEC #3	0.82	0.81	**98%**

Decision Making Framework



Impact

Fully automated WebApp to support efficient decision-making

PRECISION EMPOWERMENT	1) Empowering Patient Confidence *Refined drug labels empower patients*	5) Informed Risk Reduction *Expert insight into dangerous drug combinations*
	2) Vigilance in Vulnerability *Swift identification of susceptible patient subgroups*	6) Hidden Beneath the Surface *Unveiling and preventing potential adverse events*
TAILORED CARE	3) Preserving Patient Well-being *Thousands of patients spared from adverse reactions*	7) Revolutionizing Generalizations *Bridging clinical trials to real-world patient benefit*
	4) Global Influence, Individual Lives *Impact on millions through Takeda's reach*	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