AI in Pharmacovigilance

Empowerment through Automation

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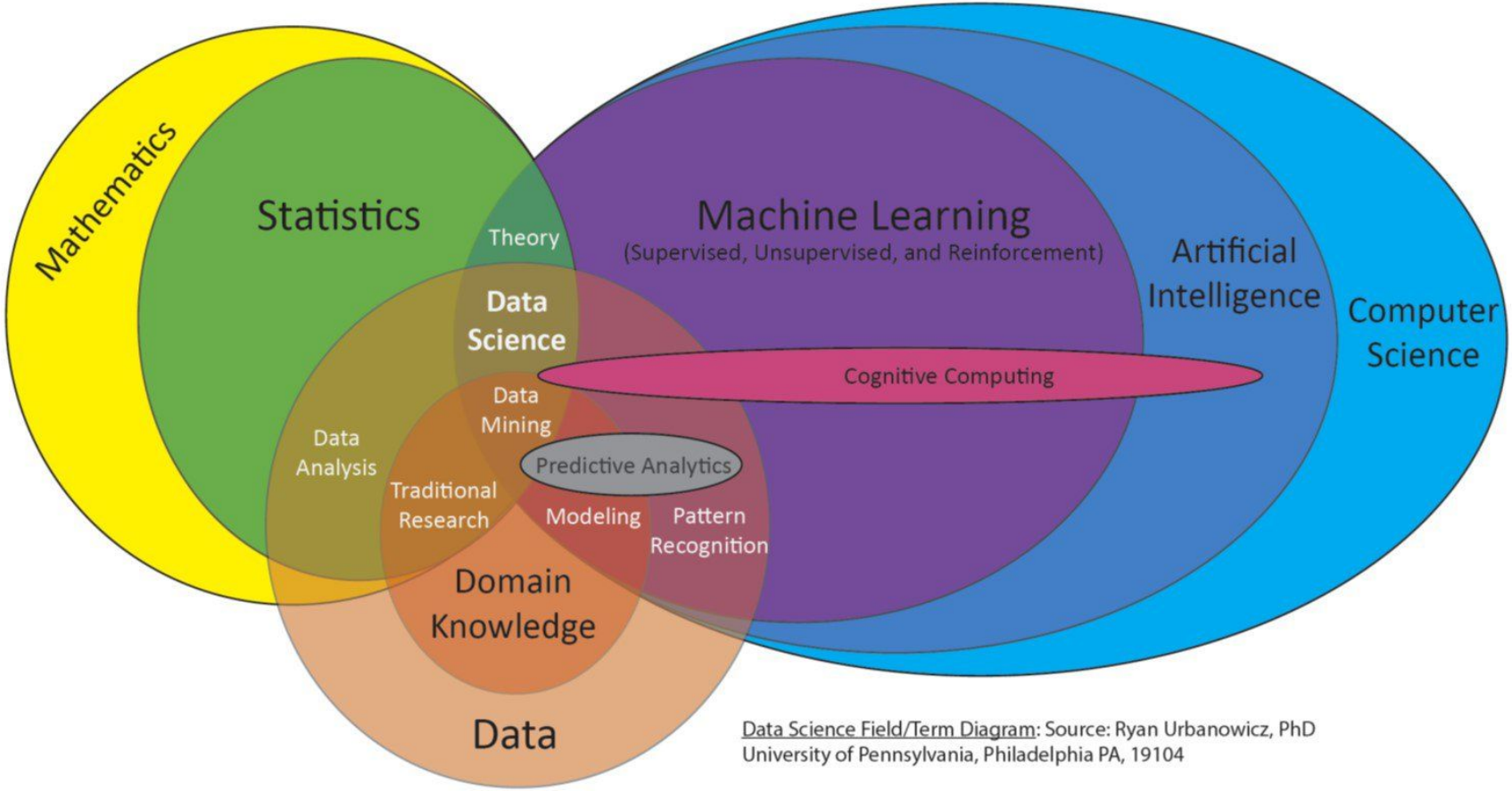
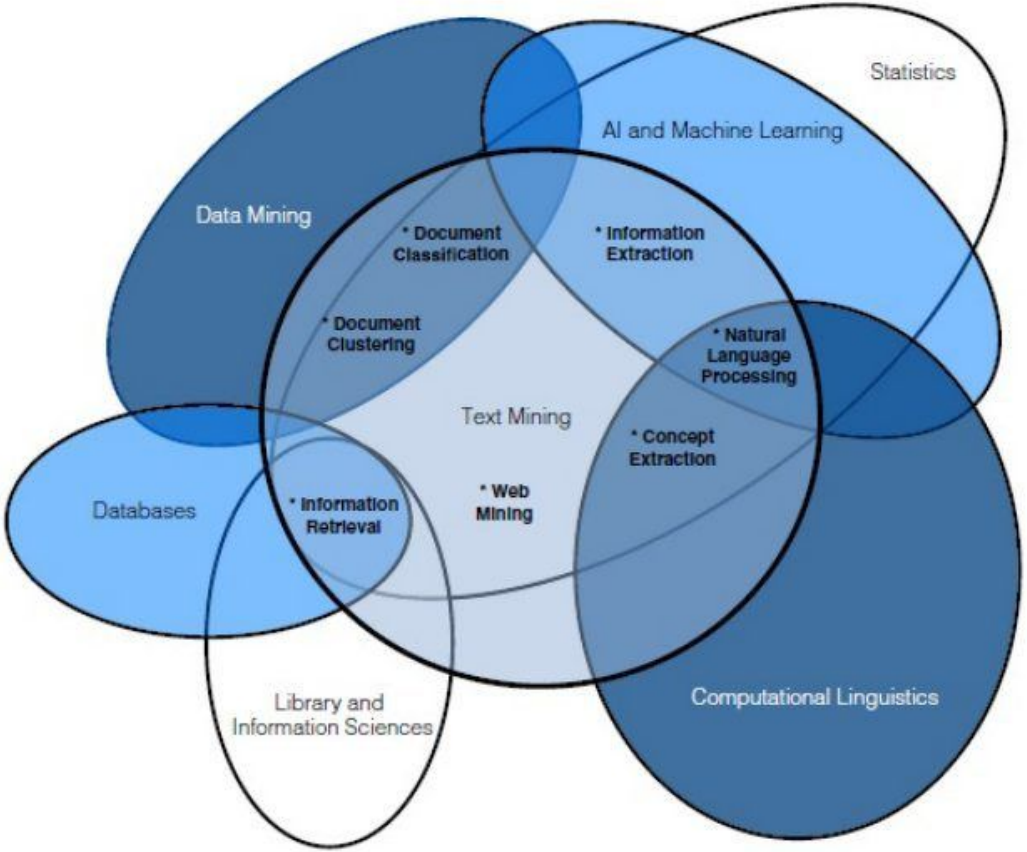
Introduction to AI & Automation

What is AI?

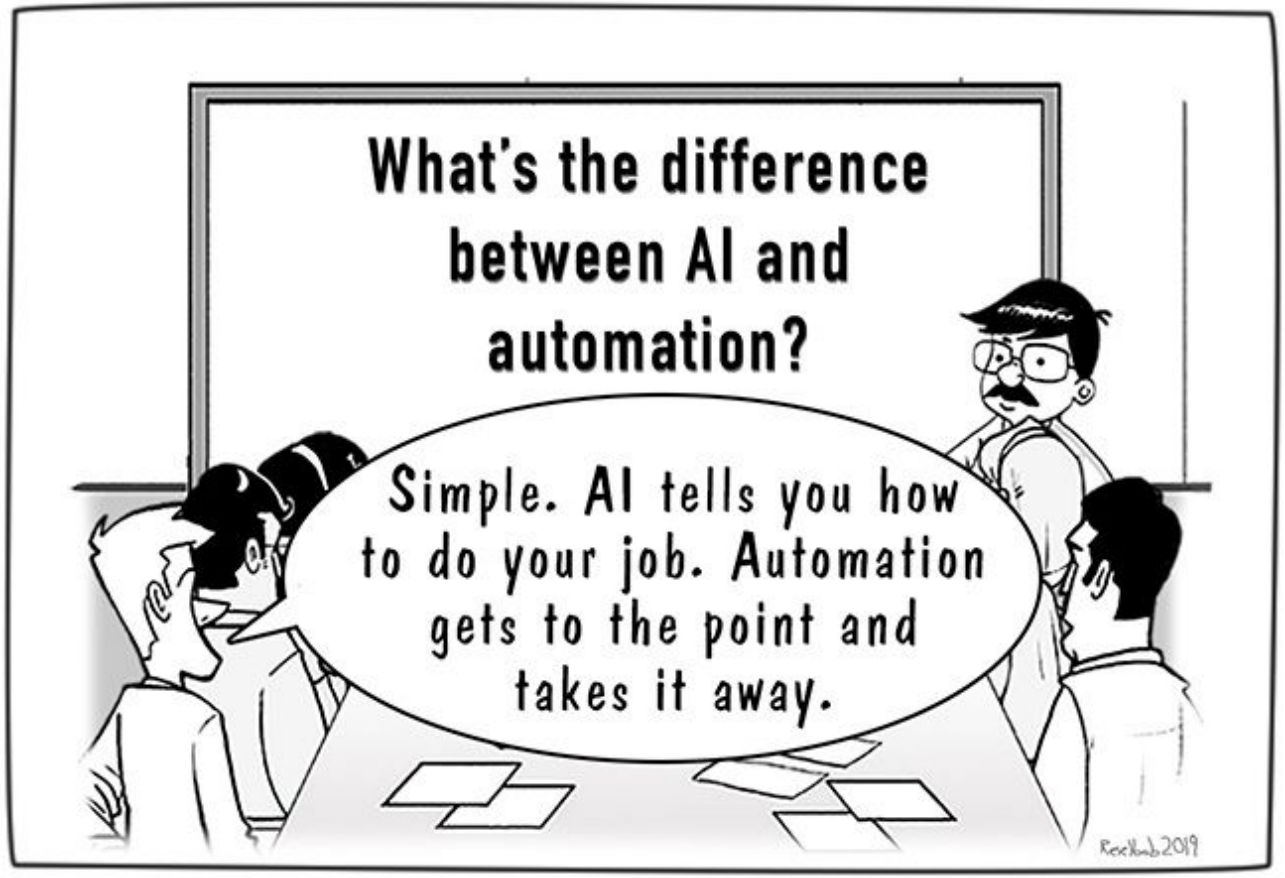


Data Science Field/Term Diagram: Source: Ryan Urbanowicz, PhD
University of Pennsylvania, Philadelphia PA, 19104

What is AI: AI & Natural Language Processing



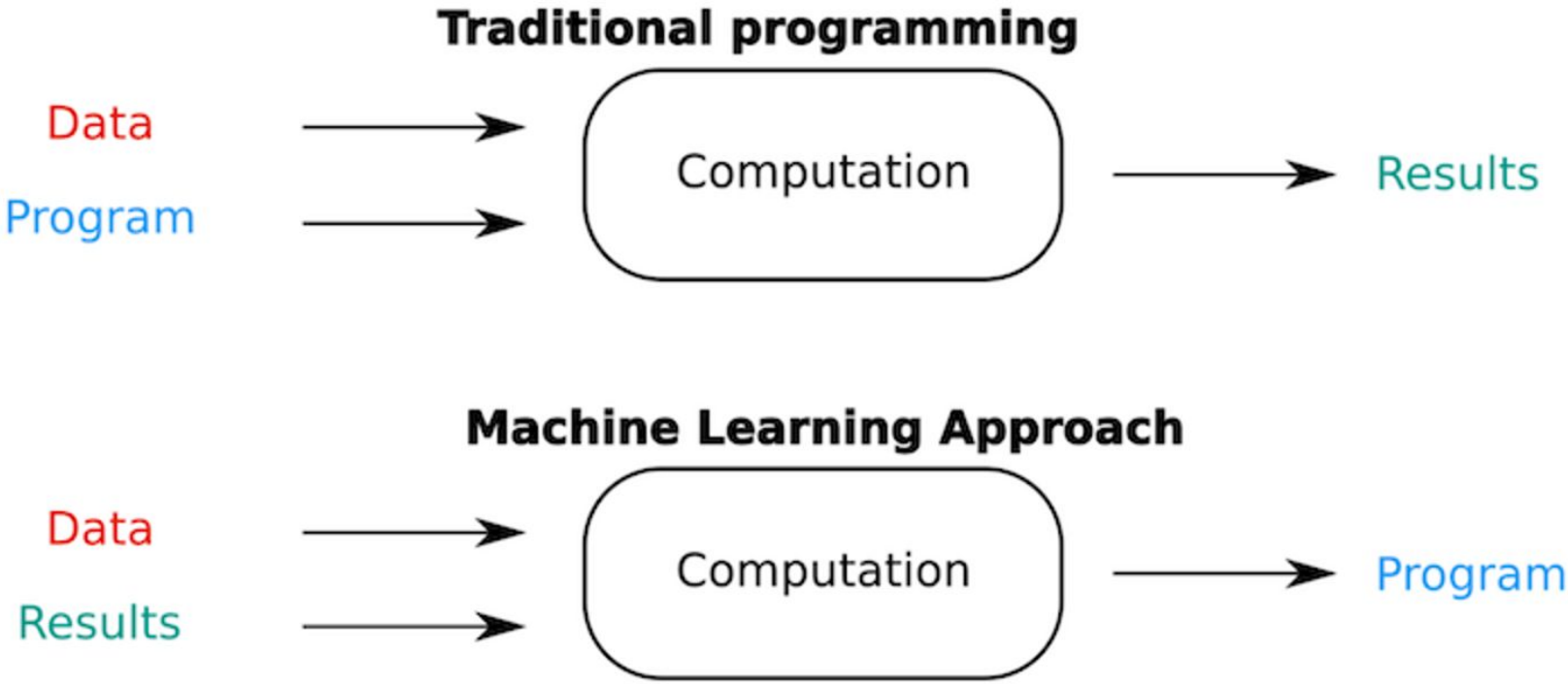
AI vs Automation



Large language Models

Large Language Models

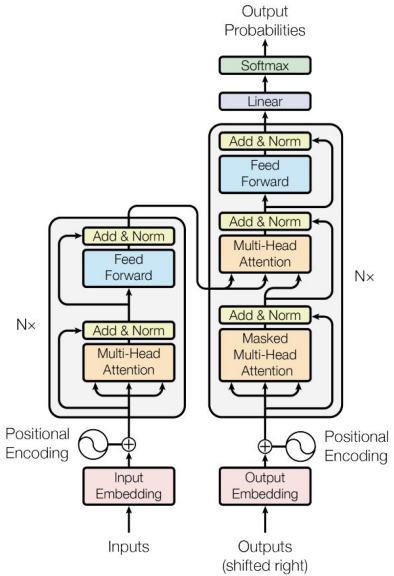
A brief introduction to Machine Learning

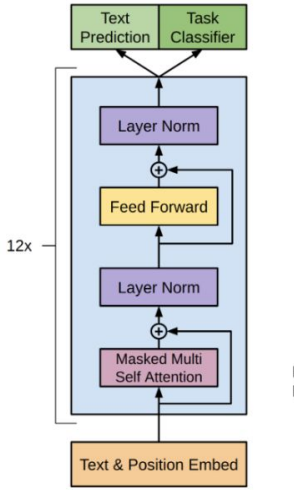


Large Language Models

What are they? How are they trained?

Large Language models are neural networks trained on large quantities of unlabeled text. LLMs are general purpose models which excel at a wide range of tasks, as opposed to being trained for one specific task (such as sentiment analysis, named entity recognition, or mathematical reasoning)

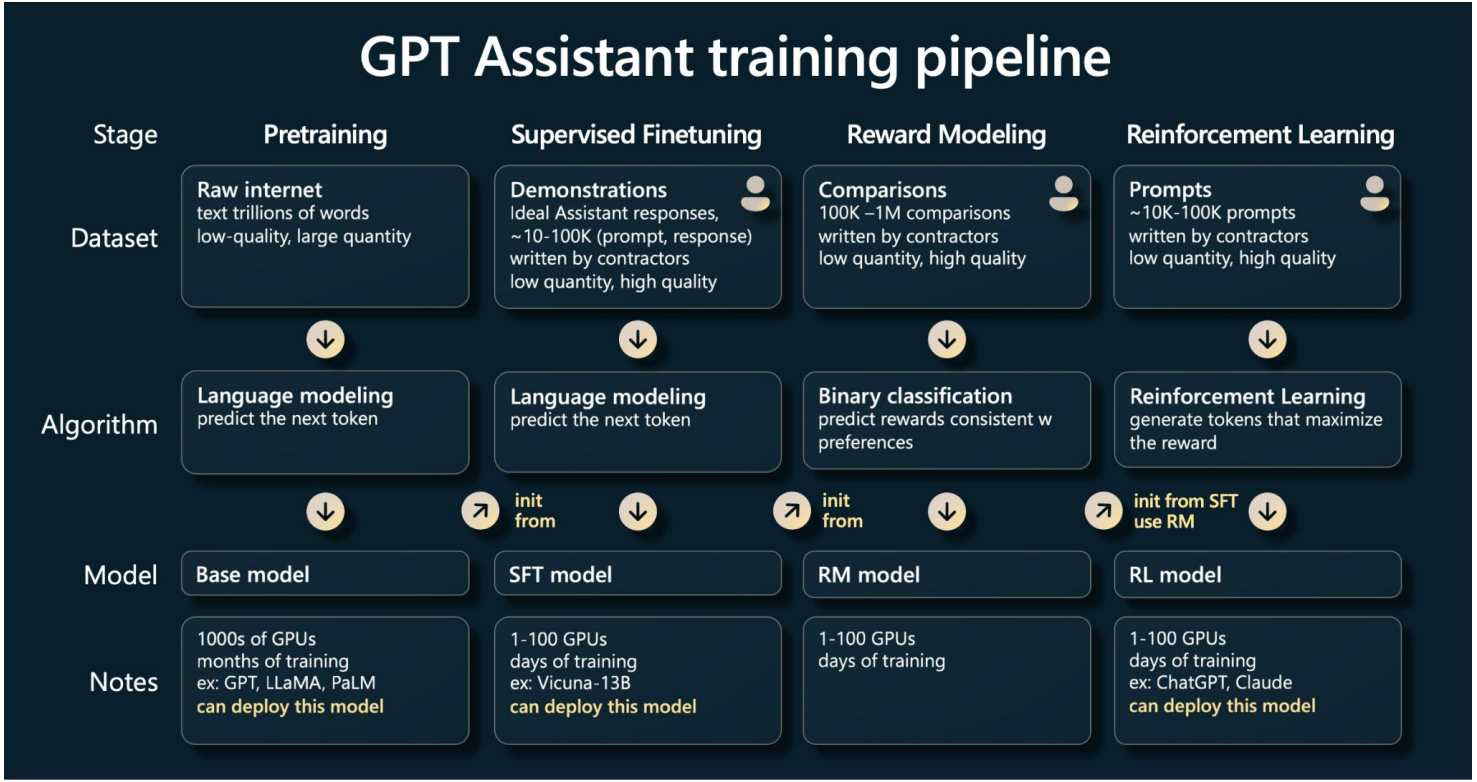




Source: Attention is all you need

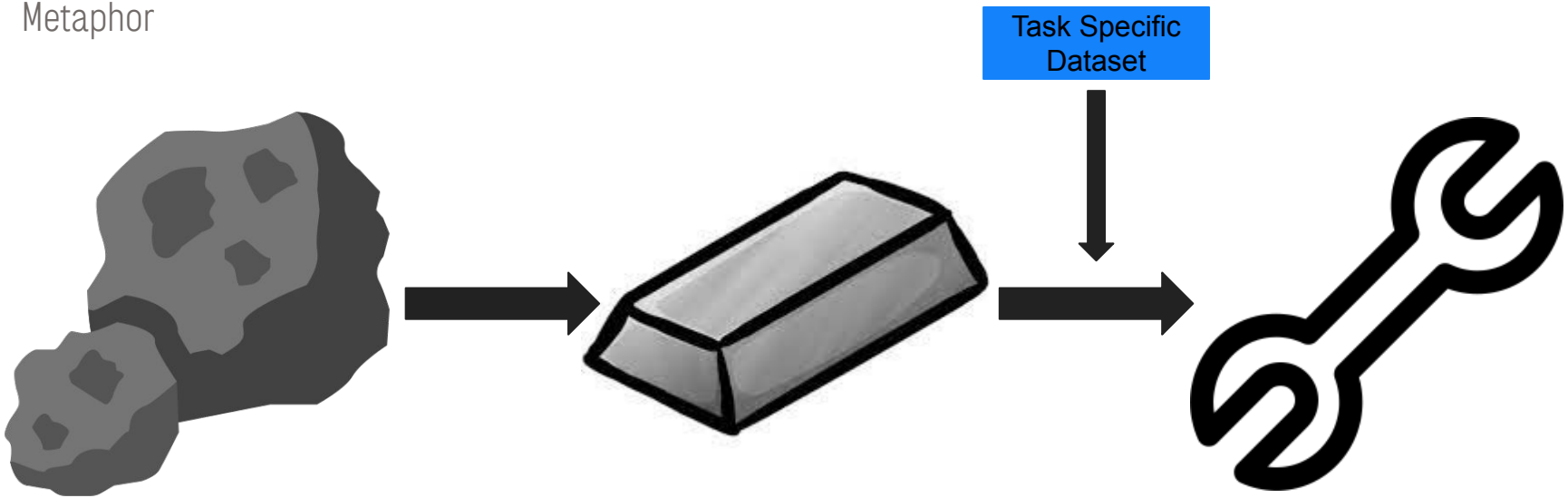
Large Language Models

What are they? How are they trained?



Large Language Models

Metaphor



Text Corpus: Wiki articles, internet data, open books corpus etc

Large Language Model: BERT, GPT, LLAMA etc

Fine Tuned Task Specific Model

Large Language Models

GPT3 & the new generation of large language models

Text Corpus: Wiki articles, internet data, open books corpus etc

Large Language Model: GPT3, LLAMA

The end of work as we know it

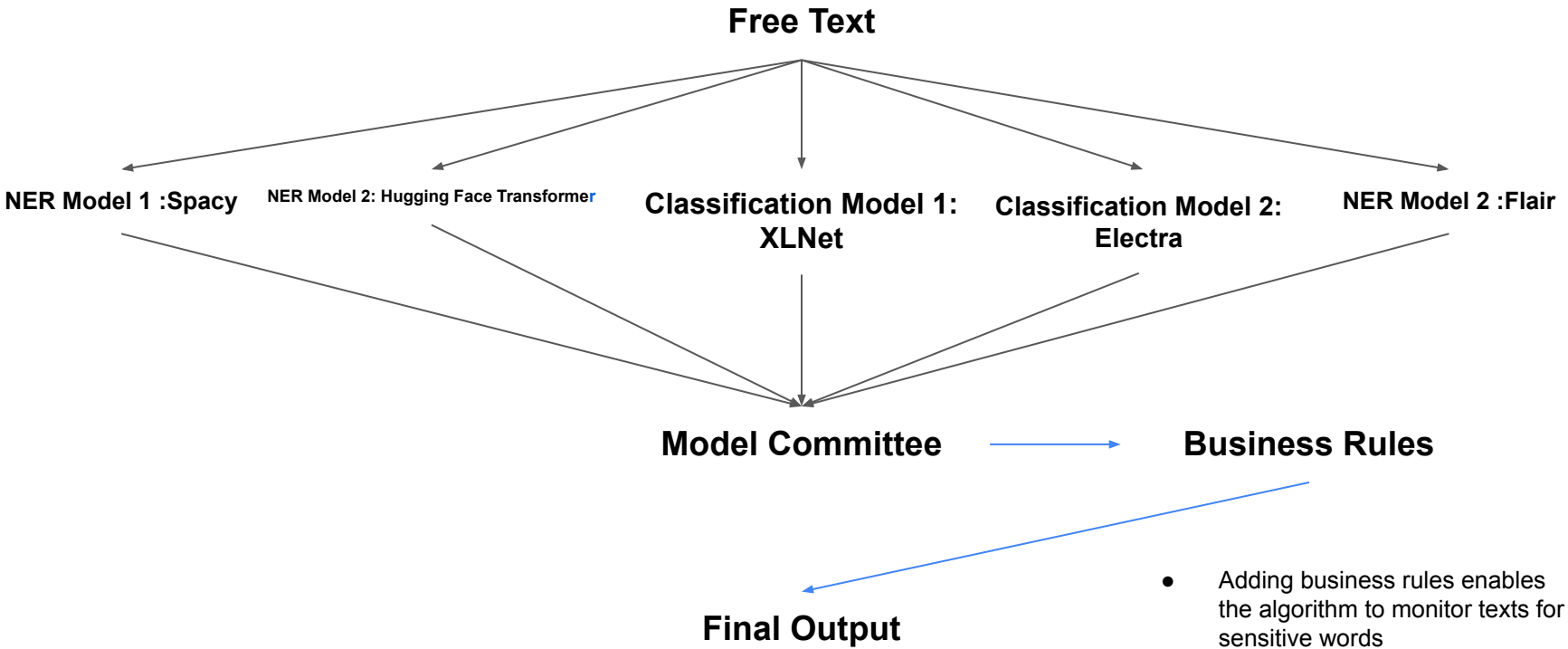
Automation & AI across the PV Value Stream

	Intake	Case Management	Submissions & Periodics	Signal Management	Safety Surveillance
AI & Machine Learning	‣ ML based AE Detection ‣ Machine translation ‣ NLP based case extraction ‣ Speech to text AE detection	‣ Touchless case processing ‣ AI Based causality ‣ AI based MedDRA and product coding	‣ NLG based Periodics report generation	‣ Neural signal detection (Predictive signalling) ‣ Deep learning to identify safety signals	‣ AI based literature article classification ‣ Social media screening
Engineered Algorithms	‣ Fuzzy & deterministic Duplicate search ‣ Process mining	‣ AEs for Special situations ‣ Process mining	‣ Smart Periodics schedules	‣ Reduce False positives and Signal leaks with enhanced detection algorithms	
Smart Automation	‣ ICR ‣ Bot assisted Follow-ups ‣ Bot assisted CTV ‣ Bot assisted Contact test	‣ Case processing rules engine	‣ Rules based submission ‣ Reconciliation ‣ Smart Periodics schedules	‣ Smart signal tracking & alerts	‣ Automated literature searches

The Common Minimum Problem in PV

Locally Optimal Solutions: AE Filter & Experiments with ChatGPT

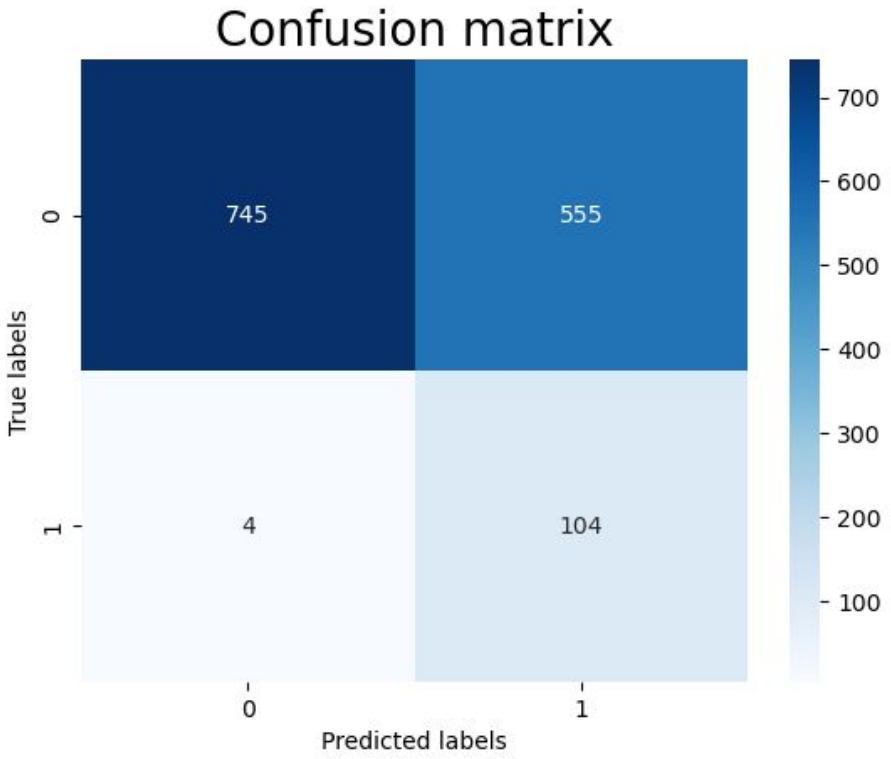
AE Filter



- Adding business rules enables the algorithm to monitor texts for sensitive words
- A list of flaggable words is maintained and searched for in texts using simple pattern matching

AE Filter

Performance

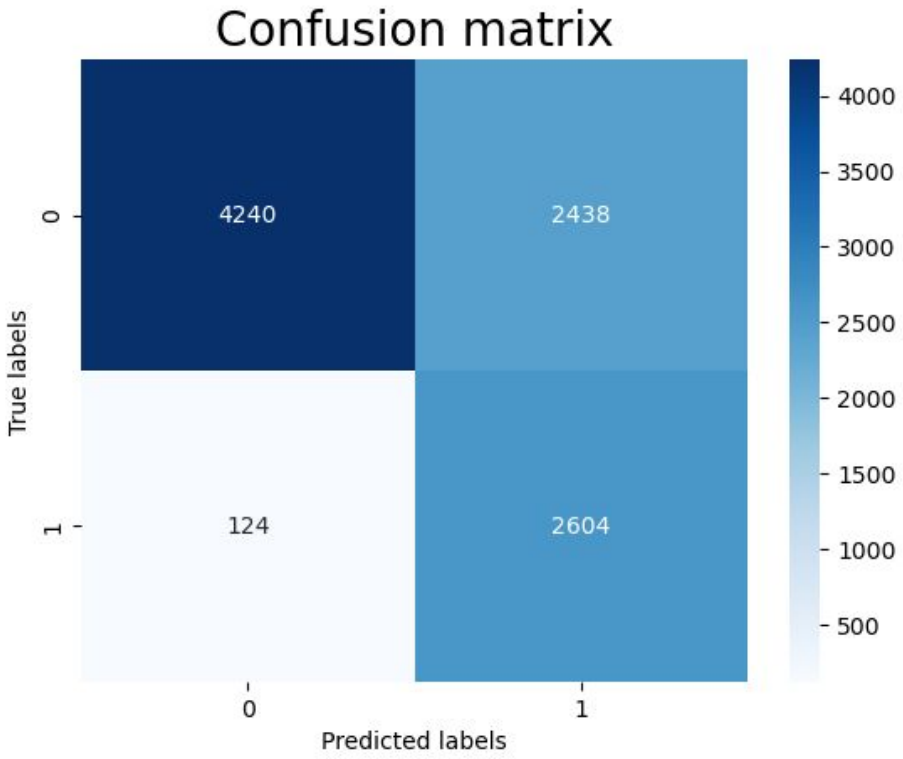


True Positive Rate = 96.42%
False Positivity rate = 42.7%

Lots of time and resources spent on curating dataset, training, testing & validating individual models.

GPT3.5 on Open Source AE Data: Experiment 1

[Link to Open Source Data]

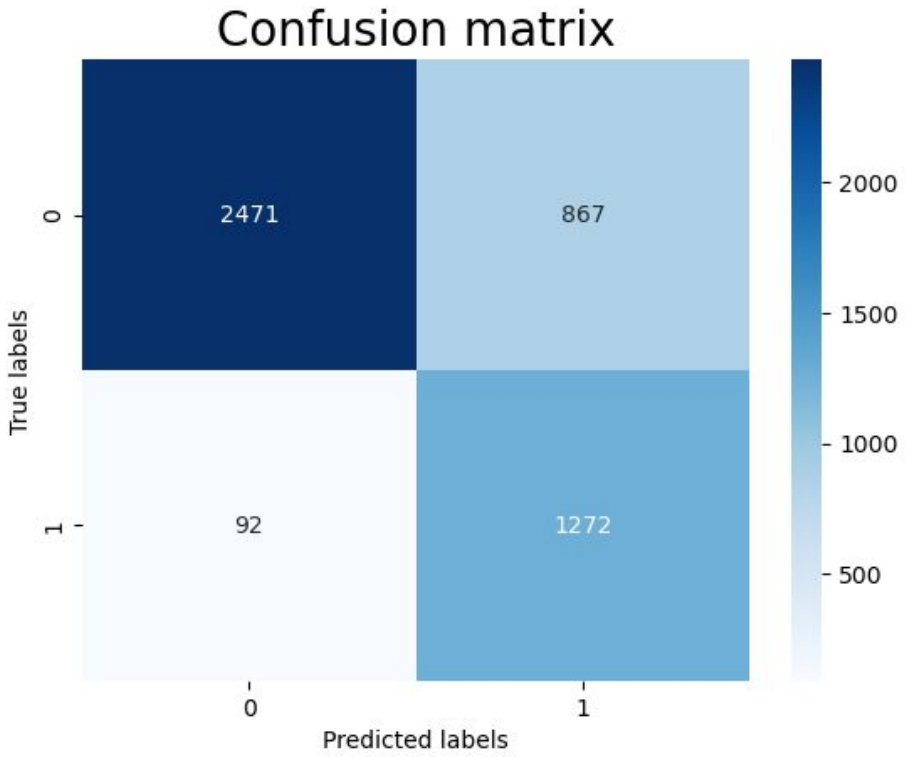


Average Efficiency Gain: 42.5%
Number of Hours Saved: 141.3
Estimated Cost: $0.8

Prompt:
You are an AI assistant that helps people classify medical. Please respond with only one word, yes or no. Does the following statement contain an identifiable pharmaceutical drug and an adverse event:

GPT3.5 on Open Source AE Data: Experiment 2

Link to Open Source Data

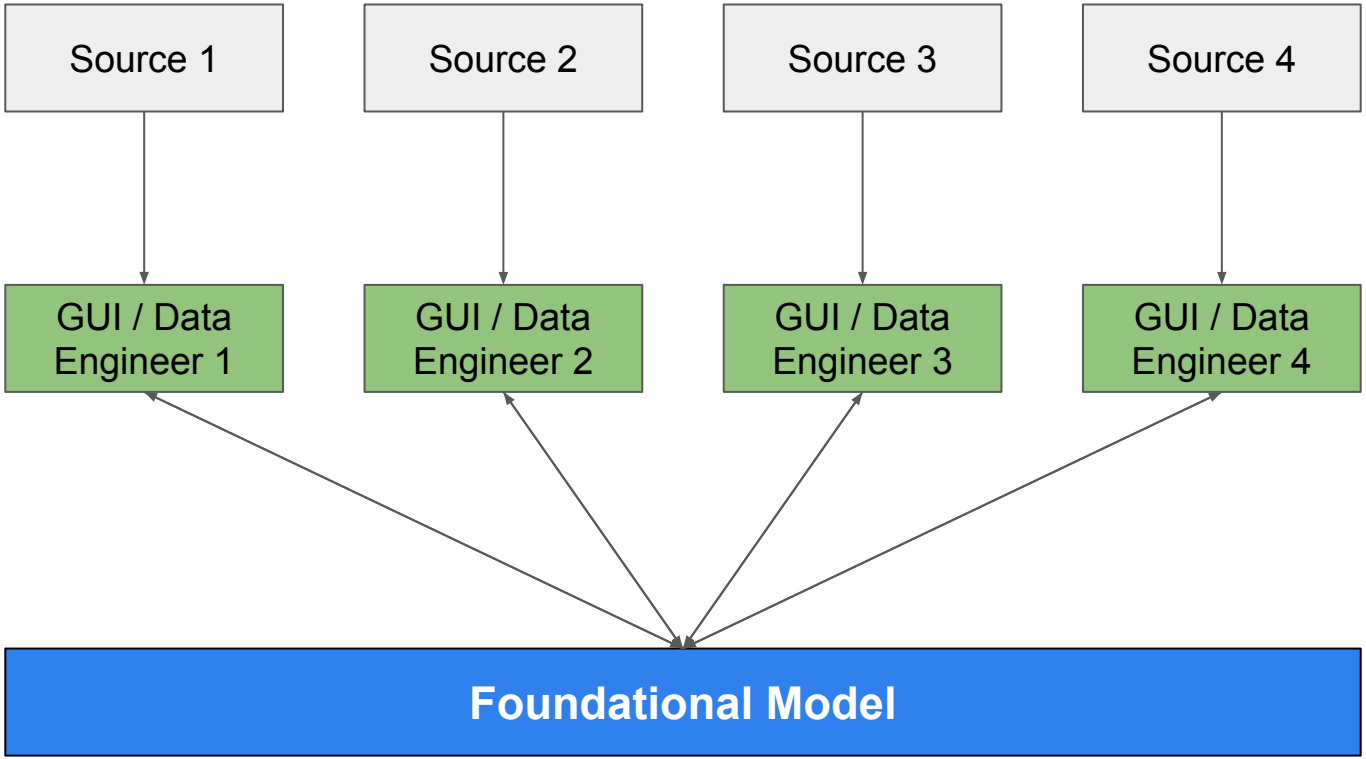


Average Efficiency Gain: 64.91%
Number of Hours Saved: 81.4
Estimated Cost: $0.4

Prompt:
You are an AI assistant that helps people classify medical. Please respond with only one word, yes or no. does the following statement contain an identifiable pharmaceutical drug ***and an adverse event caused by*** *the pharmaceutical drug:*

Locally Optimal Solutions

Using Foundational Models Appropriately



Challenges

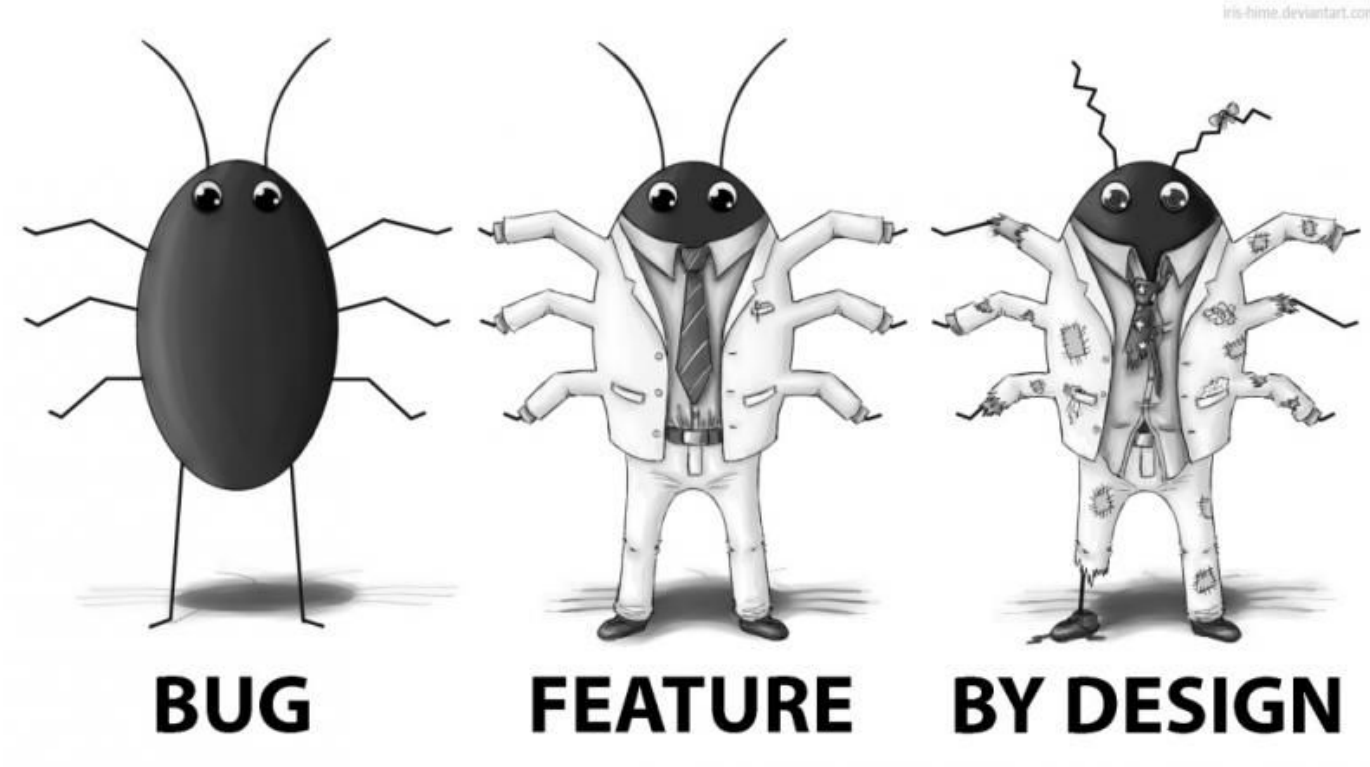
Challenges


1
Vendor maturity
Vendor maturity in the area of AI & ML combined with PV expertise is still evolving.
2
Skills & capabilities
PV professionals must learn new skills in relation to AI implementation & CSV. Close collaboration between PV professionals & technical experts is key to success
3
AI Explainability & Validation
As this technology is still evolving quickly, best practices for explainability & validation of AI based solution will emerge and evolve. Regulatory alignment is a key consideration.
4
AI performance & sustainment
AI model performance monitoring and sustainment after deployment needs to be considered in design
5
AI Act & Regulation

Lessons Learned

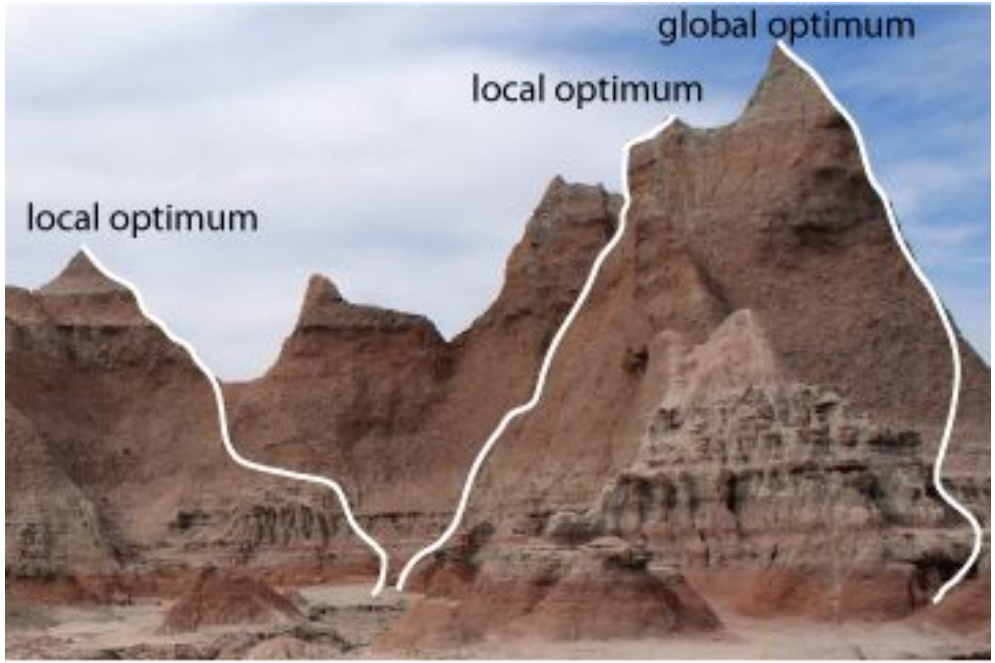
Learning From Experience

Complexity in PV Processes is not a bug. It is a Feature



Learning From Experience

Prefer Locally Optimal Solutions



Learning from Experience

Empower process owners and Data Scientists

Doing now what patients need next