

Artificial Intelligence & Pharmaceutical Industry Impacts

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AGENDA

- AI – Explained
- Who Should Care About AI?
- The AI Legal Framework and Assessing Risks
- Data Privacy Considerations

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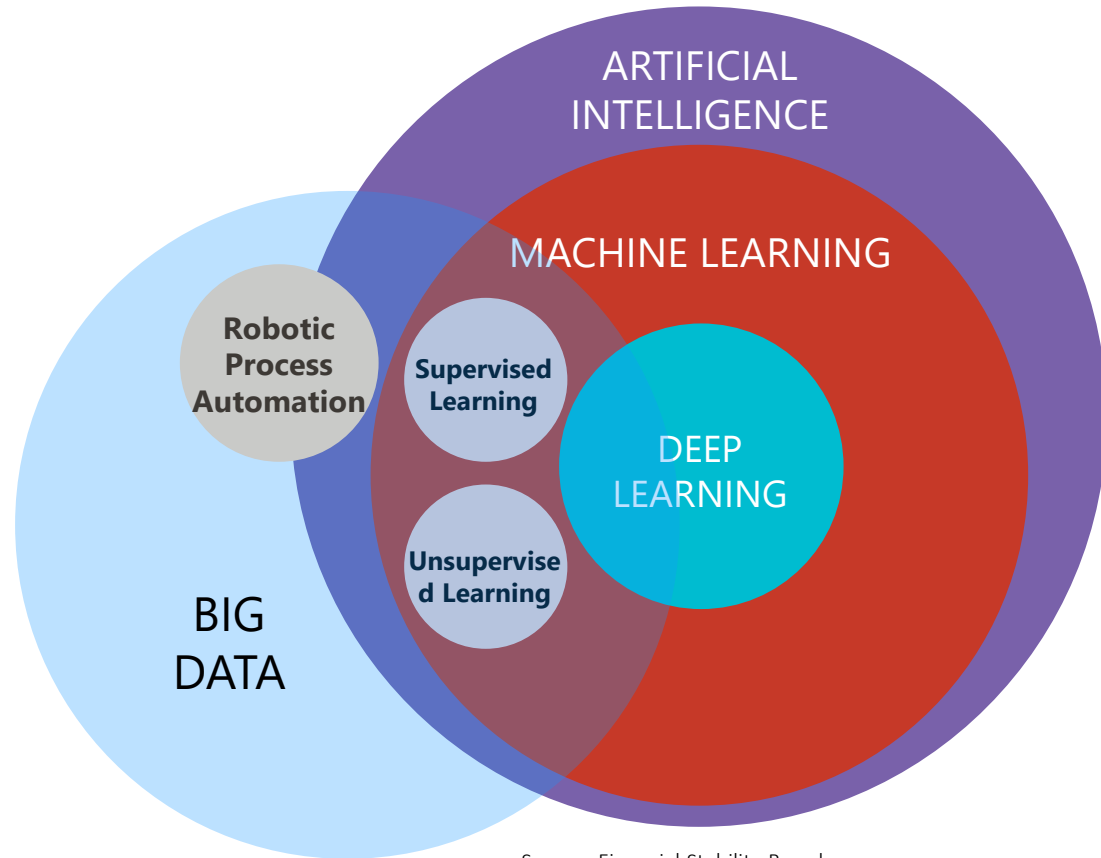
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AI – Explained



WHAT IS AI?

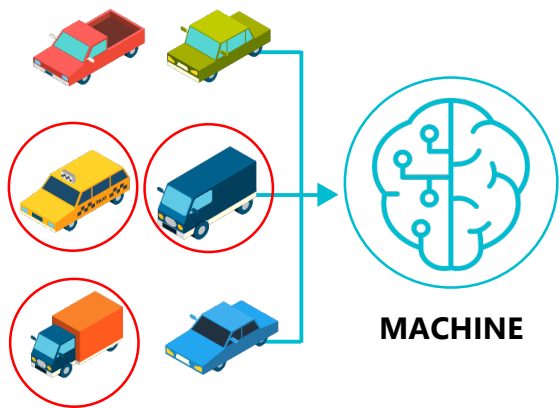
- Def. (1) Software able to perform tasks that normally require human intelligence; (2) Use of algorithms to estimate the probability of future events based on patterns found in prior data
- Generative AI vs. Discriminative AI
- Large Language Models



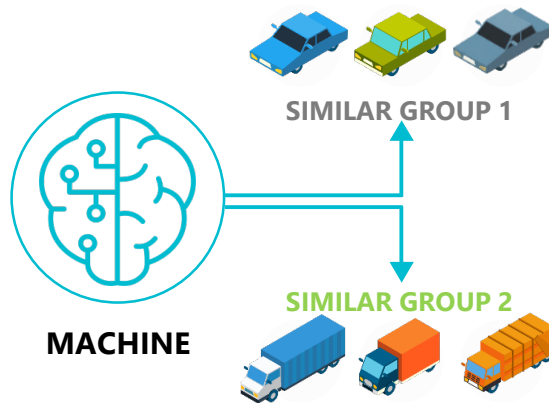
Source: Financial Stability Board

WHAT IS SUPERVISED MACHINE LEARNING?

Step 1 Provide the machine learning algorithm with input data as **labeled** "training data."



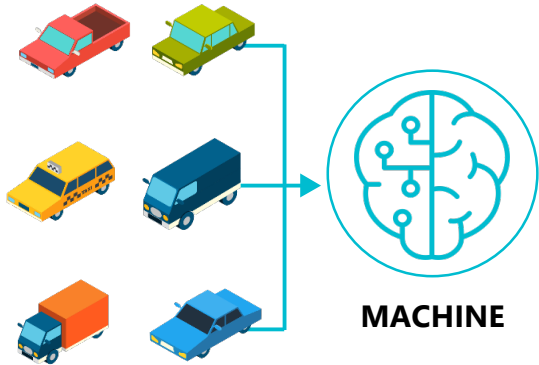
Step 2 Use the trained AI system to categorize new data.



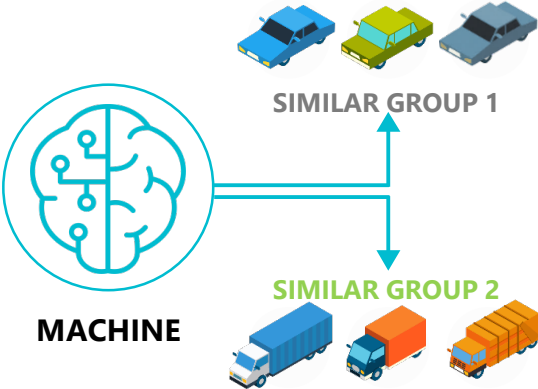
Supervised machine learning usually uses discriminative models

WHAT IS UNSUPERVISED MACHINE LEARNING?

Step 1 Provide the machine learning algorithm with uncategorized, unlabeled input data.



Step 2 Observe and learn from the patterns the machine identifies.



Unsupervised machine learning usually uses generative models

GENERATIVE AI – IMPACT

- Goldman Sachs projects generative AI will cause a [7% increase in the global GDP,- i.e., \\$ 7 trillion- over the next 10 years](#)
- 48% of CEOs (in Yale 200-CEO survey) believe **healthcare** is the industry that will be most transformed by AI, including by improving diagnosis, treatment and areas such as protein folding and drug discovery
- The Economist: "'Generative' AI, meanwhile, is being trialed for suggesting entirely new chemical and biological structures for testing in the pharma industry" [Big pharma is warming to the potential of AI, The Economist, Jul. 13, 2023](#)

USE CASE EXAMPLES

- A “use case” is a targeted application of generative AI to a specific business challenge, resulting in one or more measurable outcomes

Use Case	Measurable Outcome	Risks
Customer Operations: AI “chatbots” can be programmed to give personalized responses to complex customer inquiries regardless of the language or location of the customer and can instantly retrieve customer data	Increased speed (and potentially accuracy) in response to customer inquiries; lower volume of inquiries that require a human agent	On what data is the AI model based—is it all verified to be accurate and “explainable” or is the model making inferences and could “hallucinate”? Are there biases or discrimination inherent in the data set? At what point does an inquiry get escalated to a human agent?
Marketing & Design: Using generative AI to create content such as personalized emails to customers or advertisement campaigns	Reduced cost of generating output, increase in revenue from enhanced effectiveness of higher quality content at scale	If the AI model is trained on publicly available data, does it have sufficient safeguards in place to avoid plagiarism and IP infringement?
R&D: Pharmaceutical companies can use AI foundation models to automate preliminary screening in the lead identification stage of drug development	Researchers can use an “off-the-shelf” foundation model to more precisely cluster certain images, resulting in more efficient identification of the most promising chemicals for further analysis	Is there human oversight over the process to control for quality? Are there “known unknowns” and “unknown unknowns” accounted for in the AI model and process?

Who Should Care About AI?



AI IS NOT JUST AN “IT” ISSUE

- Determining which use cases are appropriate for the business, how AI is implemented to address those use cases, and putting into place safeguards to mitigate risks and comply with law requires attention from and coordination across various functions and roles within a company
 - How is the company executing this on a day-to-day level?
 - How is the company executing this at a governance and enterprise risk level?
 - Are people with the right skillsets in the conversation?
 - Are people with relevant roles/oversight within the company receiving substantive training to get up to speed on the ever-evolving AI landscape?
 - How are consultants/outside experts being used?



AI IS A BOARD OF DIRECTORS AND MANAGEMENT-LEVEL ISSUE

- While implementation and practical application of generative AI requires attention on a day-to-day operational level across various business functions, it does not stop there—the board and top management are also key players
- Board members can help their management team move forward by asking the right questions:
 - How is AI used by the company and its competitors? How might it disrupt the industry?
 - How should we organize for generative AI? What individual roles, committees/teams and substantive training or expertise are needed? What is our reporting structure and how do issues get surfaced up the chain?
 - What are the applicable legal and regulatory frameworks and how are we ensuring compliance?

Board Focus: Unlock the value of generative AI while also managing its risks

IMPORTANCE OF AI DISCUSSIONS IN THE BOARD ROOM

- Depending on the company's use cases for AI, AI may pose challenges to corporate policy or effectiveness or create "mission critical" risks to the business
 - Director fiduciary duty to exercise good faith and act with reasonable care to attempt to assure that management maintains appropriate systems of control (quality and otherwise) over generative AI and systems to safeguard confidential data
 - For example, using AI in financial reporting and securities filings would implicate oversight of internal controls and disclosure controls and procedures
- AI-related corporate policies and reporting mechanisms must be carefully crafted and adopted as applicable laws and compliance risks develop
- Record keeping in the form of board agendas and minutes documenting director exercise of oversight, as well as director and management trainings on AI-related risks and legal considerations is critical



The AI Legal Framework and Assessing Risks

GLOBAL LEGAL AND REGULATORY SPOTLIGHT ON AI

Forbes: What Biden's New Executive Order Could Mean For The Future Of AI

The federal government “is the largest procurer of vendor services in the U.S.,” [Dominique Shelton Leipzig](#), a partner and cybersecurity and data privacy leader with Mayer Brown, said via email.

Today's executive order “will directly impact trillions of dollars in government contracts. It goes well beyond IT to include life sciences,, defense contracts, landlords and more. To give a sense of scale, the government spent \$2 trillion on IT services alone last year,” she pointed out.

If a company “is (1) a recipient of federal funds; (2) part of critical infrastructure (health, financial, energy, food supply); (3) a government contractor; or (4) a supplier to any of [these] companies...their leaders need to pay attention,” Leipzig advised.

AI Safety Summit 2023 Agenda

Day 1 – The Summit will commence with opening remarks from the UK Government, other nations at the frontier of AI development and the UK's Frontier AI Taskforce. Delegates will then break out for roundtable discussions regarding understanding and improving frontier AI risks. The day concludes with a panel discussion titled “AI for good – AI for the next generation”.

Day 2 – The UK Prime Minister will convene a small group of governments, companies and experts to discuss what steps can be taken to address the risks in emerging AI technology and ensure it is used as a force for good. At the same time, Michelle Donelan, the UK Secretary of State for Science, Innovation and Technology, will reconvene international counterparts to agree next steps.

GLOBAL LEGAL AND REGULATORY SPOTLIGHT ON AI

- Currently, there are AI legal frameworks pending in 37 countries and across six continents
 - This is on top of the historic (circa 2016) AI-laws already in place across 127 countries
- In the US, there were 146 state and federal bills pending in state capitols and the US Congress in H1 2023; US key guidance is “The Blueprint for an AI Bill of Rights”, published by the White House
 - Connecticut and California have passed legislation affirming commitments to the AI Bill of Rights
- The Consumer Financial Protection Bureau, Department of Justice, Equal Employment Opportunity Commission, Food and Drug Administration, Federal Trade Commission and the Securities and Exchange Commission have issued guidance or otherwise indicated through enforcement activity that they view AI as within their purview of their current regulatory and enforcement authorities
- The EU is the furthest advanced in terms of finalization of new AI-related laws: EU Artificial Intelligence Act (“EU AI Act”) was passed in June 2023 (not yet in effect as law)

WHY AI LEGAL FRAMEWORKS MATTER

- What is the upshot of the hundreds of proposed legal frameworks pending all over the world?
 - AI-related regulation seeks to balance the interest in encouraging innovation with concerns about human rights and civil liberties, including privacy rights, anti-discrimination interests, consumer safety and protection, intellectual property protection, information integrity, security and fair business practices
- What are the potential consequences of non-compliance?
 - Monetary fines: AI non-compliance penalties are projected to be larger than the GDPR's highest fine levels of 4% of a company's gross revenue, which have totaled over 4 billion Euros in fines (the current EU Parliament proposal is 7% of a company's gross revenue)
 - Reputational damage
 - In certain cases, personal liability

WHAT RISK LEVEL IS EACH USE CASE?



EXAMPLES OF HIGH-RISK (“YELLOW LIGHT”) AI

Health AI Use Cases

1. Pharmaceutical use
2. Health
3. Family planning and care
4. Genomic data
5. Biometric data
6. Processing genetic/biometric data to identify individuals
7. Genetic data concerning health
8. Data or metadata regarding health
9. Data and metadata generated by *technologies* used in the health domain
10. Data and metadata that can be used to infer data from health inputs
11. Disability-related data
12. M-health
13. Medical devices
14. In vitro diagnostic medical devices

HR AI Use Cases

15. Employment
16. Vocational training
17. Workers’ rights
18. Trade union membership
19. Employee monitoring
20. Legal Status
21. Custody
22. Divorce information
23. Immigration

Surveillance AI Use Cases

24. Behavioral data
25. Monitoring home, school, environments

Sensitive Data AI Use Cases

26. Racial or ethnic origin
27. Religious or philosophical beliefs.
28. Sex life or sexual orientation

29. Relationship history
30. Data and metadata generated by technologies used in a sensitive area
31. Data and metadata that can be used to infer data from a sensitive domain
32. Geolocation data

Manufacturing AI Use Cases

33. Machinery
34. Lifts
35. Equipment
36. Protective systems intended for use in potentially explosive atmospheres
37. Radio equipment
38. Pressure equipment
39. Recreational craft equipment
40. Cableway installations
41. Appliances burning gaseous fuels
42. Autonomous robots

EXAMPLES OF HIGH-RISK (“YELLOW LIGHT”) AI (CONT’D)

Financial AI Use Cases

- 43. Personal finance
- 44. Data that could have the reasonable potential to be used in ways that are likely to expose individuals to meaningful harm, such as a loss of privacy or financial harm due to identity theft
- 45. AI systems used to evaluate credit scores or creditworthiness

Children’s AI Use Cases (*Data or Meta Data Does Not Need to Be Sensitive for Kids*)

- 46. Numerical,
- 47. Text,
- 48. Image,
- 49. Audio, or
- 50. Video data
- 51. Toys
- 52. Child rights. Article 24 EU Charter; UN Convention on the Rights of the Child

AI Use Cases Adversely Impacting Fundamental Rights

- 53. Dignity
- 54. Respect for private and family life
- 55. Protection of personal data
- 56. Freedom of assembly and of association
- 57. Non-discrimination
- 58. Consumer protection
- 59. Right to effective remedy

Criminal Justice AI Use Case

- 60. Judicially pre-authorized law enforcement use of post-remote biometric identification system (e.g., using video surveillance systems equipped with facial recognition technology to recognize a person from a pre-populated database)
- 61. AI for sentencing recommendations, or suspect identification
- 62. Right to a fair/ speedy trial
- 63. Right to a defense

- 64. Presumption of innocence

AI Impacting Democracy

- 65. AI impacting the rule of law
- 66. Freedom of expression and information
- 67. Political opinions

Critical Infrastructure AI Use Case

- 68. Other Critical Infrastructure
- 69. Power grids
- 70. The transport network and
- 71. Information and communication systems.
- 72. Hospitals
- 73. Energy
- 74. Food Supply

AI GOVERNANCE FOR HIGH-RISK AI

Step 1: Categorize Risk Level of AI Use Case

Prohibited, High Risk, Minimal or Low Risk



Step 2: High Quality Data Definition is “relevant” and material



Step 3: Pre-and Post-Deployment Continuous Testing, Monitoring, Auditing

Algorithmic bias, Accuracy, Consumer product/health/safety, IP, Privacy, Cybersecurity, Antitrust



Step 4: Requires Technical Additions to Be Made to the AI System Technical Logging and Documentation for High-Risk AI Systems. Mitigation steps should be reflected in the technical documentation



Step 5: Human Oversight Modify the AI if Steps 3-4 reveal deviations from expectations, humans need to correct the model



Step 6: Failsafe Company needs the ability to stop the AI use case if deviations cannot be corrected



SPOTLIGHT ON STEP 3: CONTINUOUS TESTING, MONITORING, AUDITING

Continuous monitoring enables *management* to continually review business processes for adherence to and deviations from their intended levels of performance and effectiveness.

Continuous auditing enables *internal audit* to continually gather from processes data that supports auditing activities.

Deloitte.

Continuous monitoring and
continuous auditing
From idea to implementation

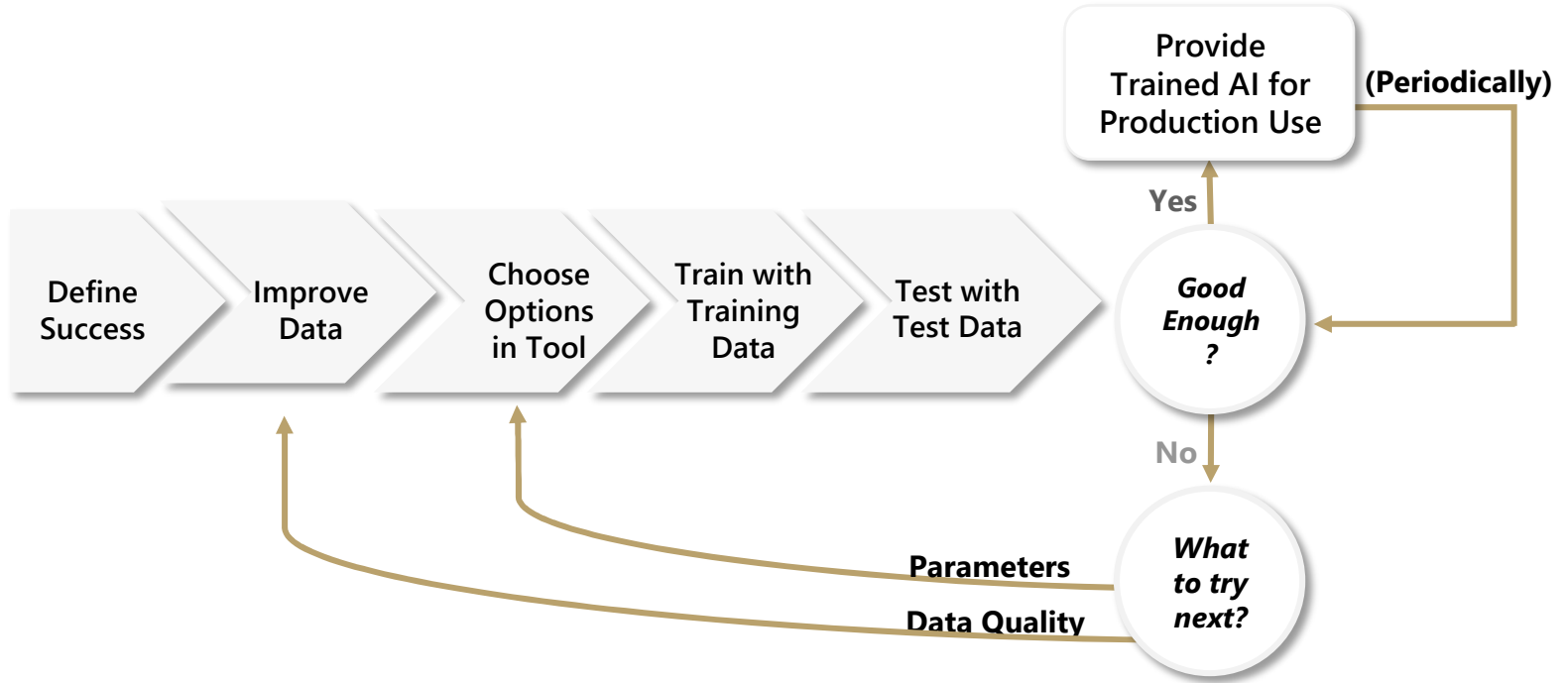
AI GONE WRONG

- In 2018, Amazon's AI-recruiting tool used to score candidate resumes was found to be gender-biased. The model was trained to vet applicants by observing patterns in resumes submitted to the company over a 10-year period, over which period most resumes came from male applicants
- In 2019, NY state officials launched an investigation into whether UnitedHealth Group's Optum algorithm had a racial bias – a study found that the algorithm used to assign risk scores gave the same risk level to Black patients as it did to white patients who were healthier
 - The Letter from NY officials stated: "By relying on historic spending to triage and diagnose current patients, your algorithm appears to inherently prioritize white patients who have had greater access to healthcare than black patients."
 - The algorithm resulted in recommending less preventative care for Black patients vs. white patients by over 50%
- In 2023, an attorney used ChatGPT to research court case precedents, and at least six of the cases cited in his brief did not exist and were a byproduct of ChatGPT "hallucinations"

BENEFITS OF EARLY ADOPTION OF AI LEGISLATIVE TRENDS FOR HIGH RISK AI

- The technology is new—it can hallucinate, and behave differently in the wild than as planned. Continuous testing, monitoring, auditing, gives your company an opportunity to avoid being the next case study for “AI gone wrong”
- Brand protection and preservation—evidence of your AI governance program will exist within the technical documentation for the AI system itself
- Regulatory lenience
- Provides arguments for defense
- Less likely that exorbitant fines would be imposed
- Good governance can lead to great results
 - [In January 2023, AbSci became the first entity “to create and validate *de novo* antibodies *in silico*” using generative AI](#)
 - [In February 2023, the FDA granted its first Orphan Drug Designation to a drug discovered and designed using AI; Insilico Medicine plans to begin a global Phase II trial for the drug “early” this year](#)
 - [In March 2023, headlines reported “Generative AI Finds Potential Cancer Drug – in 30 Days”](#)

MANAGING AI SUCCESS





AI GOVERNANCE IS A TEAM SPORT

- AI Governance teams could consider collaborating now with colleagues who have expertise in the areas that will be required for testing (bias, IP, privacy, cyber, accuracy, product safety, antitrust)
- Enable the capacity to test within AI systems themselves
- Have correct team members engaged
- Keep the Board informed
- Keep GC informed
- Keep CEO informed



Data Privacy Considerations

GENERAL DATA PRIVACY CONSIDERATIONS

- Privacy notices / lawful basis to use
- Consumer rights (including opt-out for automated decision making that produce legal or similarly significant decisions)
- Contractual obligations
- Data minimization / Retention / Purpose Limitation / Privacy-by-Design
- Data Protection Impact Assessments



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