

What is Artificial Intelligence?

US National AI Initiative Act of 2020

The term “artificial intelligence” means a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. AI systems use machine and human-based inputs to— **(A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action**

China’s AI Standardization White Paper

[The] theories, methods, technologies, and application systems for using digital computers or digital computer-controlled machines to **simulate, extend, and expand human intelligence, perceive the environments, acquire knowledge, and use knowledge to obtain the best results.**

IBM

“At its simplest form, artificial intelligence is a field, which combines computer science and robust datasets, to enable problem-solving. It also **encompasses sub-fields of machine learning and deep learning, which are frequently mentioned in conjunction with artificial intelligence.** These disciplines are comprised of AI algorithms which seek to create expert systems which make predictions or classifications based on input data.”

European Commission

“AI refers to systems that display intelligent behavior by **analyzing their environment and taking actions - with some degree of autonomy** - to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications).”

Luncheon Mini Summit 22: Responsibly Harnessing the Power of AI

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Ethical AI in Pharma: A Roadmap for Compliance

The pharma industry has an incredible opportunity to maximize the potential of AI responsibly and ethically

What compliance can do ...

- 1 Define how the company will approach ethics as it relates to AI (align culture, principles, standards)
- 2 Define AI relevant to the company's actual use of it
- 3 Embed identified principles within the company and communicate our expectations to third-party partners
- 4 Consistently review/adapt principles to ensure ethical behavior throughout rapidly evolving tech advancements

What compliance can deliver ...

-  Governance, operating model for the ethical use of AI
-  Principles, policies, framework, risk considerations and education
-  Monitoring and remediation framework

Appendix

**EU AI Act:
First
Regulation on
AI**

Specific Objectives

- AI in EU market is safe and respects existing EU law
- Legal certainty to facilitate investment and innovation in AI
- Governance and effective enforcement of EU law on fundamental rights and safety requirements applicable to AI systems
- Single market for lawful, safe and trustworthy AI applications and prevent market fragmentation

Overall Status of the Act

- Currently in draft
- In June 2023, MEPs adopted Parliaments negotiating position
- Talks will now begin with EU countries in the Council on the final form of the law
- Aim is to reach an agreement by end of year
- Proposed penalties up to 7% of global turnover

EU AI Act: Different Rules for Different Risks

- **Unacceptable Risk**

- **Prohibited AI Practices:** AI considered a threat to people and will be banned
- Cognitive behavioral manipulation/subliminal techniques
- Exploitation of vulnerable groups (e.g., physical or mental disability)
- Social Scoring
- Real-time remote biometric ID in public by law enforcement (exceptions apply)

- **High Risk**

- **AI negatively affecting safety or fundamental rights**
- Used in products under EU's product safety legislation (e.g. med devices, toys, aviation) OR 8 specific areas
- **Requirements:** database registration, ex-ante conformity assessment, risk management, testing, technical robustness, data training and governance, transparency, human oversight, cybersecurity, authorized representative

- **Limited Risk**

- AI Examples: Chatbots, emotion recognition systems, biometric categorization, and AI that generates or manipulates media (i.e. deepfakes)
- Allow users to make informed decisions and decide whether to continue using
- **Requirements:** Minimal transparency

- **Low/Minimal Risk**

- No obligations (under AI Act)
- Act envisages creation of code of conduct that encourages voluntary application of high-risk AI requirements

Pyramid of Risks

