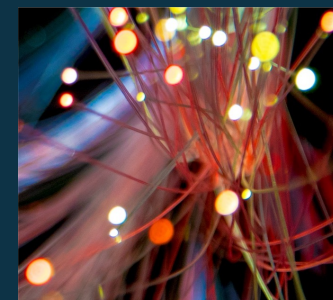




Navigating Global Regulations for AI/ML

Implications on Clinical Research

May 7th, 2024



Agenda

- Background & Context
- Need for Regulation
- Key global Regulatory Trends & initiatives
- Landmark Global regulations & Guidance
- Good Machine Learning Practice (GMLP)
- WHO's 6 principles
- Guidance & Best practices
- Conclusion



Background & Context

What got us here?

Perceptron (First Modern Neural Network), 1957

- a single-layer neural network capable of learning and making simple decisions

ELIZA, 1965

- Developed by Joseph Weizenbaum at MIT, ELIZA is an early example of a natural language processing program.

General Problem Solver (GPS), 1969

- The General Problem Solver is developed by Allen Newell and Herbert A. Simon, demonstrating a problem-solving approach in AI that uses heuristics and search algorithms.

Neural Networks Resurgence, 1987

- The backpropagation algorithm experiences a resurgence, leading to advancements in training multilayer perceptrons

Google's DeepMind Atari Breakthrough, 2014

- DeepMind's AI agents learn to play Atari 2600 games at superhuman levels

Stanford's Stanley Wins DARPA Challenge, 2005

- Stanford University's autonomous vehicle, Stanley, wins the DARPA Grand Challenge.

Deep Blue vs. Garry Kasparov Chess Match, 1996

- IBM's Deep Blue supercomputer competes against chess grandmaster Garry Kasparov in a historic match.

Reinforcement Learning Breakthrough, 1992

- Reinforcement learning gains recognition as an effective technique in AI

GPT-2 Language Model Release, August 2019

- OpenAI releases GPT-2, an advanced text generation model, raising concerns about the potential misuse of AI-generated content

Waymo's Fully Autonomous Taxi Service Launches, October 2020

- Waymo launches a fully autonomous taxi service called Waymo One in the Phoenix area, offering rides to the general public,

ChatGPT Debut, November 2022

- OpenAI debuts ChatGPT, an AI chatbot built on top of the GPT-3.5 large language model, advancing the capabilities of conversational AI

OpenAI's First-Ever Dev Day, November 2023

- Among many announcements, the company releases the ability for users to build custom GPTs which can be augmented and tailored to specific use cases.



Need for Regulation

What are we trying to safeguard ourselves from?

Safety & Security

AI systems can pose risks to safety and security.

Safeguard from malicious actors for harmful purposes

Fairness & Accountability

Prevent bias and discrimination

Promoting Accountability & Transparency

Consumer Protection

Protection for consumers from harmful AI applications

Ensure safety, reliability & beneficial

Privacy & Data Protection

Individual's privacy

Collection, use and storage of individual data

Ethical Considerations

Impact on employment

Social equity & Human Rights

Promoting Innovation

Balance between Safety & Innovation

Ensure responsible use of AI/ML

Key Global Regulatory Trends & Initiatives

As identified by EY's AI Global Regulatory Landscape Report

Trend 1: The OECD principles for AI serve as a global benchmark for AI guiding policymakers

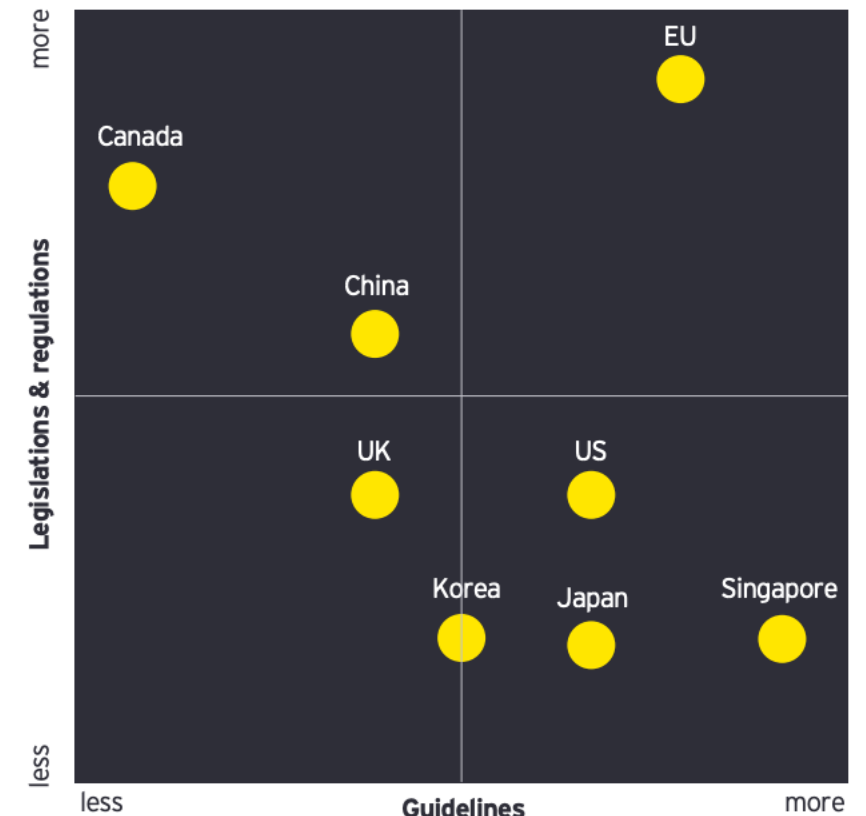
Trend 2: Policymakers are adopting a risk-based approach to AI

Trend 3: Policymakers are considering sector-specific considerations in AI oversight

Trend 4: Regulators are increasingly considering how AI impacts other policy areas (e.g., data, cybersecurity, and digital content flows)

Trend 5: Regulators are increasingly using sandboxes to enable the responsible testing of AI innovations

Figure 2: Approaches to AI rulemaking



Source: [ey-the-artificial-intelligence-ai-global-regulatory-landscape.pdf](#)

Landmark Regulations – EU AI Act

Timelines

The European Parliament, Commission and Council reached a political agreement on the EU Artificial Intelligence Act 8 Dec. 2023.

Once in force, it is likely to be the world's first comprehensive regulation of AI.

Key Dates

Entry into force 20 days after publication in the Official Journal of the EU.

Entry into application 24 months after entry into force, except for specific provisions.

The Commission plans to launch an AI Pact, which will commit AI developers on a voluntary basis to implementing key obligations of the AI Act prior to entry into application

Prohibitions on unacceptable risk AI.

6 Months

Commission implementing act on post-market monitoring.

18 Months

36 Months

12 Months

Obligations on providers of general-purpose AI models go into effect.

24 Months

Member states to have implemented rules on penalties, including administrative fines

End of 2030

Source : [eu_ai_act_timeline.pdf](#) (iapp.org)

Confidential



Landmark Regulations – EU AI Act

High-level elements in the agreement

**General
purpose AI**

Governance

Prohibitions

**High-risk
systems**

**Human rights
impact
assessment**

Transparency

Fines

Source: [EU reaches deal on world's first comprehensive AI regulation \(iapp.org\)](https://iapp.org)

Other Governmental Initiatives

US and Other Countries

China

- 2022: Beijing Consensus on Artificial Intelligence and Education
- 2022: Provisions on the Administration of Algorithm Recommendation of Internet Information Services in China

Japan

- 2020: Guidelines on Assessment of AI Reliability in the Field of Plant Safety
- 2019: AI Utilization Guidelines

Singapore

- 2020: AI Governance Testing Framework Minimum Viable Product
- 2019: National AI Strategy

United Kingdom

- 2022: Establishing a pro-innovation approach to regulating AI
- 2021: National AI Strategy
- 2019: Guide to using Artificial Intelligence in the public sector

United States

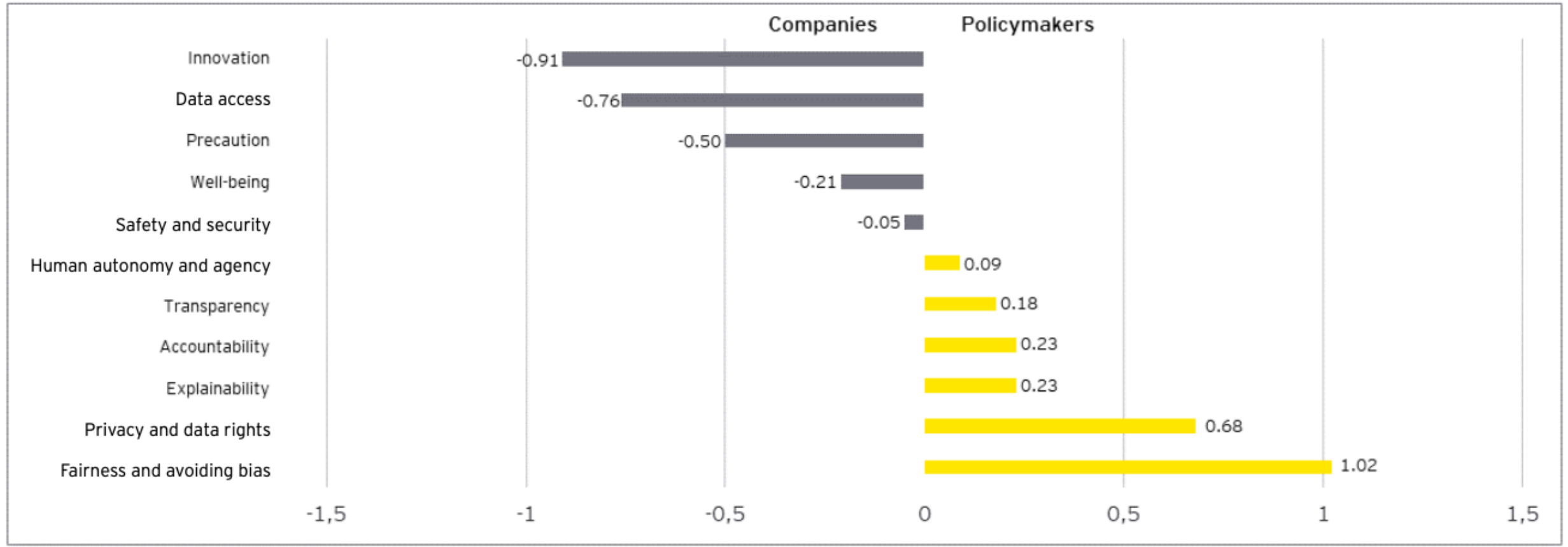
- 2024: On April 29, 2024, NIST released a draft publication based on the AI Risk Management Framework (AI RMF) to help manage the risk of Generative AI
- 2023: NIST AI risk management framework
- 2022: Blueprint for an AI Bill of Rights
- 2022: Artificial Intelligence and algorithmic fairness initiative



Ensuring Compliance

Trust gap between Companies and Policymakers

Relative importance of ethical principles



Source: [ey-the-artificial-intelligence-ai-global-regulatory-landscape.pdf](#)

Framework for Medical Product Development

WHO's 6 principles for an AI Regulatory Framework

Documentation
& Transparency

Risk
Management

Validation

Data
Considerations

Privacy & Data
Protection

Engagement &
Collaboration

Sources: [WHO's 6 Principles For An AI Regulatory Framework For Medical Product Development \(meddeviceonline.com\)](https://www.meddeviceonline.com); [Regulatory considerations on artificial intelligence for health \(who.int\)](https://www.who.int)



Good Machine Learning Practice (GMLP)

■ Introducing new GxP practice?

- A set of principles and best practices for developing and deploying machine learning (ML) models, particularly in the context of medical devices and healthcare
- The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that inform the development of GMLP for medical devices that use artificial intelligence and machine learning (AI/ML)
- Joint guidance published in 2021

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

Source: [Guiding Principles - GMLP \(fda.gov\)](https://www.fda.gov/guidance/guiding-principles-gmlp)

Guidance & Best Practices

EYs Trusted AI Framework

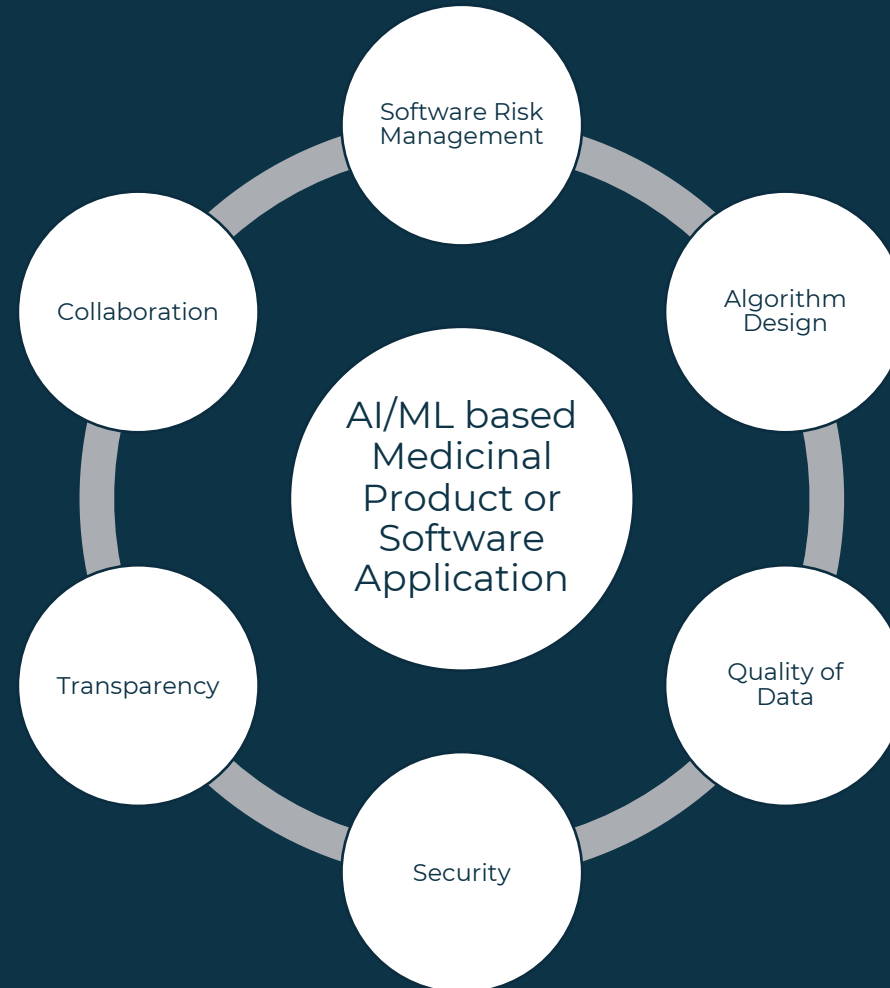
Leading practices for establishing trusted AI ecosystem

1	AI advisory board	AI advisory board is a multi-disciplinary advisory board providing independent advice and guidance on ethical considerations in AI development. Advisors should be drawn from ethics, law, philosophy, technology, privacy, regulations and science. The advisory board should report to and/or be governed by the Board of Directors.
2	AI design standards	AI ethical design policies and standards for the development of AI, including an AI ethical code of conduct and AI design principles. The AI ethical design standards should define and govern the AI governance and accountability mechanisms to safeguard users, follow social norms and comply with laws and regulations.
3	AI inventory and impact assessment	An inventory of all algorithms, including key details of the AI, that is generated using software discovery tools. Each algorithm in the inventory should be subject to an impact assessment to assess the risks involved in its development and use.
4	Validation tools	Validation tools and techniques to confirm the algorithms are performing as intended and are producing accurate, fair and unbiased outcomes. These tools can also be used to monitor changes to the algorithm's decision framework.
5	Awareness training	Educating executives and AI developers on the potential legal and ethical considerations for the development of AI, and their responsibility to safeguard impacted users' rights, freedoms and interests.
6	Independent audits	Undergoing independent AI ethical and design audits by a third-party against your AI and technology policies and standards, and international standards to enhance users' trust in your AI system. An independent audit would evaluate the sufficiency and effectiveness of the governance model and controls across the AI lifecycle from problem identification to model training and operation.

Source: [ey-the-artificial-intelligence-ai-global-regulatory-landscape.pdf](#)

Keys to Regulatory Approval

Enablers to obtaining fast regulatory approval and commercialization



Conclusion

Recommended next steps

- AI / ML is the future we must live in
- Many regulations applicable for data privacy, security etc. will be applicable
- Innovation is moving at a fast pace and Regulations will always play catch-up
- Our obligation to prioritize ethical considerations, like we always do
- Comprehensive strategy with heavy focus on risk, validation & compliance
- Organizational change management & Training
- Agility and Nimbleness are the keys to success



Our Contact

Keep in touch with us

Venu Mallarapu
VP, Global Strategy & Operations
eClinical Solutions



vmallarapu@eclinicalsol.com



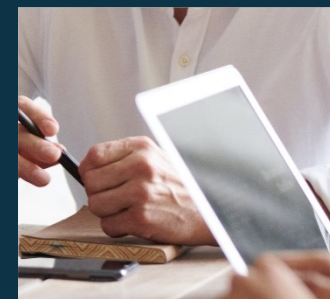
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Thank you

