Global AI regulations: Decoded for life sciences companies

What the evolving rules mean for your strategy

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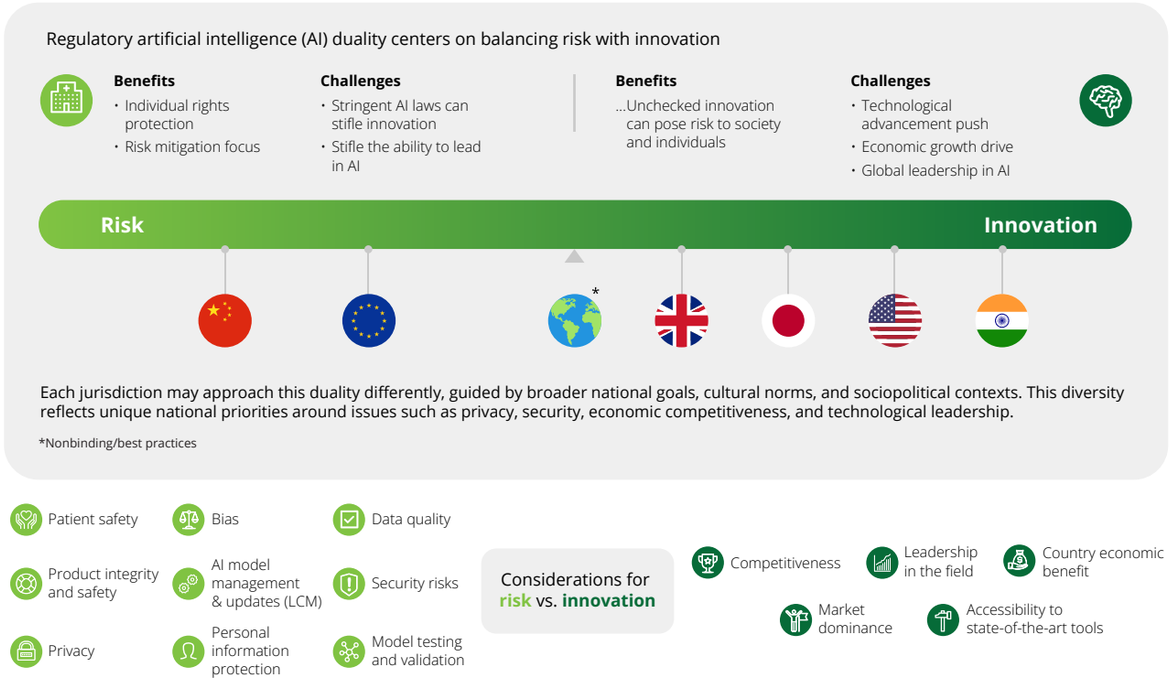
Introduction

The global artificial intelligence (AI) revolution has moved from theoretical potential to operational reality—especially for the life sciences sector. The AI tools reshaping how therapies and medical devices are developed, tested, and brought to market are now subject to rising and broad global regulatory oversight. At the center of this transformation lies what GRIT*—the Global Regulatory Intelligence Team at Deloitte—calls the AI duality: the mounting tension between innovation and risk aversion (figure 1).

Figure 1: The AI duality

The duality between risk and innovation



* GRIT (Global Regulatory Intelligence Team) is a Deloitte initiative and community of practice that leverages Deloitte's global regulatory and quality experience to help life sciences clients navigate the increased complex global regulatory environment. With a network of more than 300 professionals in 30 countries, GRIT assists clients in their respective regions by providing global and local insights to navigate challenges with the ever-evolving life sciences regulatory landscape.

Every jurisdiction we explored through our research, which spanned from October 2024 through April 2025—across six global regions: China, European Union, United Kingdom, Japan, United States, and India—is pursuing a different regulatory approach and is in a different position on the duality spectrum. Governments are eager to lead in AI innovation to spur economic growth and be at the forefront of advancement. Yet, with that ambition comes a growing recognition that AI must be deployed responsibly, with safeguards that uphold human rights, safety, transparency, integrity, and public trust. Each jurisdiction may approach this duality differently, guided by broader national goals, cultural norms, and sociopolitical contexts. The range reflects unique national priorities around issues such as privacy, security, economic competitiveness, and technological leadership. This duality is defining a new regulatory era—one in which life sciences companies should move fast without breaking what matters.

This paper represents a continuation of GRIT's commitment to exploring how regulatory shifts reshape the life sciences landscape. In early 2024, GRIT published a forward-looking point of view titled "Generative AI regulations in life sciences,"[1] based on global research concluded in late 2023. That paper mapped out the emerging contours of global AI governance as the world began to shift from voluntary, undefined principles to the emergence of enforceable mandates.

This report is a follow-up and expansion. It explores the current moment—mid-2025—as a pivotal inflection point. There's been progress in defining country-specific AI approaches, but a global, harmonized approach remains elusive. Life sciences companies face a complex global regulatory mosaic—different definitions, risk categorizations, regulatory approaches, and documentation standards across borders. The result? Life sciences leaders should build AI systems that can comply and stretch across jurisdictions while remaining resilient in the face of constant change.

GRIT's methodology in this report follows the same methodology as the early 2024 report. It includes deep dives into the same six priority jurisdictions—United States, European Union, United Kingdom, China, Japan, and India—as well as analysis of cross-border regulatory and standards-setting organizations such as International Organization for Standardization (ISO), World Health Organization (WHO), and National Institute of Standards and Technology (NIST). The following pages detail not only which AI regulatory developments have transpired in each region since late 2023, but also what these changes mean for life sciences companies as they consider global strategic planning, operational execution, and long-term competitiveness in the AI era.

As the pace of global AI regulation accelerates, one truth becomes clear: In life sciences, agility and accountability are no longer trade-offs. They are twin imperatives for the future.

Executive summary

Global AI regulations: Decoded for life sciences companies

Executive summary and outlook: The new shape of AI regulation in life sciences

The global landscape for AI in life sciences is shifting rapidly—not only in scope but in speed, scrutiny, and stakes. In some of the jurisdictions covered in this report, regulators are moving to replace voluntary frameworks with enforceable laws, while others are adopting a nonstatutory approach (table 1). AI tools that once operated globally in regulatory ambiguity—whether used in drug discovery, diagnostics, or patient monitoring—are now subject to new oversight demands that span transparency, accountability, and safety.

The approaches vary and are summarized in table 1: The European Union's AI Act is now partially in force and may classify some life sciences AI tools as high risk.[2] China's draft AI Law imposes state-driven guardrails on health-related AI. In the US, AI regulations are primarily being shaped by executive orders coming out of the White House and interpreted by multiple agencies. In Japan, the first AI law was officially introduced in 2025 and represents a significant step to establish a legal framework for the development and application of AI technologies but is still aligned with the "soft law" approach. India is advancing sector-specific guidelines and legislation. Each framework offers a unique path, but they are all shaped by the same underlying tension and duality: the drive to lead in AI innovation while avoiding missteps that could compromise patient safety, outcomes, or public trust.

And yet, the global regulatory landscape remains in flux. No steady state has been reached. While jurisdictions are converging on some high-level principles—such as privacy, fairness, transparency, and bias mitigation—common ground on enforcement and implementation remains elusive. Health authorities in some regions have issued nonbinding guidance or industry-specific high-level regulations, offering limited clarity. Currently, life sciences companies are navigating without a globally harmonized roadmap.

In addition to a high-level overview, this paper also provides deep-dive sections for each of the six jurisdictions, highlighting the evolving AI regulatory frameworks, identifying key authorities, and outlining each jurisdiction's emerging approach to AI regulation and the development of statutory mandates. The paper also dedicates a section to the global regulatory standard-setting organizations and the need for a unified global approach to AI leading practices.

Importantly, the paper also spotlights real-world use cases in which life sciences companies are already applying AI to drug development, clinical trials, and post-market safety—and explores how those use cases intersect with current global regulatory expectations. The assessments revealed some inconsistency points between jurisdictions requirements such as data-quality gaps, lack of internal model governance, and difficulties aligning AI use cases to all regional regulatory expectations. They also highlight potential practical solutions to this misalignment such as the importance of building flexible, auditable AI models from the outset, engaging regulators early, and leveraging regional tools like the UK's AI sandbox or Japan's implementation guidance.

Table 1: Global AI regulations: Decoded for life sciences companies

Jurisdiction	Key provisions published to date	Overall AI regulatory approach	Risk-innovation score*		
			Statutory	Non-statutory	Score
NORTH AMERICA					
US	• White House Executive Order (EO) 14179: *Jan 2025*[3] • FDA guidance—"Considerations for the Use of AI to Support Regulatory Decision-Making for Drug and Biological Products": *Jan 2025*[4] • FDA guidance—"Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations": *Jan 2025*[5]	**Federal:** The US is pursuing a non-statutory AI approach led by the White House EOs interpreted by agencies. In the life sciences industry, agencies such as the Department of Health and Human Services (HHS) and the Food & Drug Administration (FDA) translate these directives into operational guidelines in the absence of overarching AI legislation.		✓	**Innovation-leaning:** • Nonstatutory approach at the federal level—the US leans on flexible EOs and agency guidelines such as FDA/HHS rules • State statutory approach 8
	• In 2024, 31 states adopted resolutions or enacted legislation regarding artificial intelligence[6] • 2025 state legislation[7]	**States:** Parallel to the federal approach, states are developing regulatory frameworks to protect their citizens.	✓		

*On a 10-point scale; 1 = Most risk-averse and regulation heavy and 10 = Most innovation-oriented and light-touch
** Nonbinding best practices

Jurisdiction	Key provisions published to date	Overall AI regulatory approach	Risk-innovation score*			
			Statutory	Non-statutory		Score
EUROPE						
EU	• EU AI Act: *Aug 2024 to Aug 2027 (gradual rollout)*[8] • EU reflection paper: *Sept 2024*[9] • EU GMP Annex 22: *July 2025 (draft for consultation)*[10]	The EU has adopted a statutory approach anchored by the EU AI Act, a first-of-its-kind establishment of a comprehensive regulatory framework with staged rollouts. This Act is complemented by industry-specific guidance documents. In addition, the EU is in the process of publishing an industry-specific regulation.	✓		**Regulation-heavy:** The EU AI Act's sweeping mandates make it one of the world's most prescriptive AI jurisdictions, even with pro-innovation tools like sandboxes and phased rollouts	4
UK	• UK AI Framework: *Feb 2024*[11] • UK AI Playbook: *Jan 2025*[12]	The UK's AI Framework is a cross-sector, outcome-based, nonstatutory framework. This approach leverages existing laws and sector expertise to balance innovation with safety and ethics.		✓	**Innovation-oriented:** The UK's approach/framework balances principles of safety and ethics while fostering innovation, with plans to introduce future regulations, likely targeting the most advanced foundation AI models	6

*On a 10-point scale; 1 = Most risk-averse and regulation heavy and 10 = Most innovation-oriented and light-touch
** Nonbinding best practices

Jurisdiction	Key provisions published to date	Overall AI regulatory approach	Risk-innovation score*			
			Statutory	Non-statutory		Score
ASIA						
China	• NMPA Guiding Principles for the Classification of AI Medical Software Products: *July 2021*[13]	China balances agile regulation with state control. China's agile approach allows its Cyberspace Administration to quickly enact statutory rules to solve specific AI issues.	✓		**Regulation-heavy:** China's binding statutory rules on algorithms, deep synthesis, and AI enforce mandatory compliance while offering innovation through process agility	3
India	• Information Technology Act, 2000[14] • Digital Personal Data Protection Act, 2023[15] • Sectoral guidelines from regulatory bodies like the RRI and SEBI[16]	India has taken a nonstatutory, guidance-led stance on AI: Rather than enacting a dedicated AI law, it relies on acts and existing sectoral regulations and voluntary guidelines.		✓	**Most Innovation-oriented:** India's approach emphasizes adaptability—balancing innovation with compliance	9
Japan	• Act on Promotion of Research and Development, and Utilization of AI-related Technology: *Sept 2025*[17] • Amendment of Act on the Protection of Personal Information (APPI): *April 2022*[18]	Japan's National Diet passed the Act on Promotion of Research and Development, and Utilization of AI-related Technology, commonly referred to as the "Japan AI Act," on May 28, 2025. This is the first time legislation has been enacted to promote the development of AI and address its associated risks, such as the spread of misinformation and potential misuse. Other than this law, Japan still follows "soft law" guidance.	✓		**Innovation-leaning:** Japan's first AI statute seeks to balance the promotion of artificial intelligence development with the assurance of its safety and responsible use; it still signals a lighter, pro-innovation stance than more prescriptive jurisdictions like the EU and China	7

*On a 10-point scale; 1 = Most risk-averse and regulation heavy and 10 = Most innovation-oriented and light-touch
** Nonbinding best practices

Jurisdiction	Key provisions published to date	Overall AI regulatory approach	Risk-innovation score*			
			Statutory	Non-statutory		Score
GLOBAL						
Global regulatory standard-setting organizations	• ISO + IEC: 12 standards published in 2024; 4 in 2025[19] • NIST AI 100-5 and NIST-AI-600-1: *July 2024*[20] • IEEE: 20 Standards: *Jan 2024*[21] • ISPE: GAMP5 to include AI/ML guidance: *July 2022*[22] • IDMRF: Good Machine LearningPractice for Medical Device Development: Guiding Principles: *Jan 2025*[23] • G20: Rio de Janeiro Leaders' Declaration: *Nov 2024*[24]	Globally, AI governance remains disparate: No single global authority sets binding rules, leaving jurisdictions to craft their own frameworks. Voluntary guidance from global regulatory standard-setting organizations such as ISO, NIST, and IEEE provides some harmonization across the jurisdictions.		✓	**Innovation-leaning:** Global regulatory standard-setting organizations have issued voluntary standards and frameworks rather than binding rules; they avoid heavy regulation, while encouraging responsible innovation	N/A 5**

*On a 10-point scale; 1 = Most risk-averse and regulation heavy and 10 = Most innovation-oriented and light-touch
** Nonbinding best practices

Three strategic imperatives

Life sciences companies are faced with three strategic imperatives that can shape their readiness and ability to lead in the introduction of AI effectively into their processes:

The risk-readiness imperative. "Wait and see" is no longer a viable AI strategy. To lead in innovation and capture competitive advantage, life sciences companies need to be willing to act—despite uncertainty. That starts with moving beyond speculation and toward agile implementation strategies that allow AI solutions to flex and evolve with emerging regulations. Companies should assess where AI can meaningfully enhance their operations, establish systems to monitor regulatory changes, and prioritize the development of adaptive, risk-calibrated AI models that can keep pace with the global compliance landscape.

A patchwork with purpose. Yes, global AI regulation is fragmented. No, that doesn't mean you need a different playbook for every zip code. The throughline—fairness, transparency, and accountability—runs strong across borders. Smart life sciences companies are building global governance systems that adapt locally but scale universally. Think of it less as chasing rules and more as composing music: different notes, same melody.

From compliance to competitive edge. Here's the truth: The companies winning in this new world aren't only compliant—they're prepared and adaptable. Regulation should not be viewed as something slowing innovation down; it's the thing that proves your innovation belongs on the global stage. By embracing transparency, validating models, and addressing bias from day one, leaders are turning red tape into runway. In life sciences, where credibility is currency, regulatory readiness is your sharpest edge. Those that align early may find their competitive edge comes not from cutting corners but from building trust—at record speed.

Moving forward

Life sciences companies should embrace and prepare for continued change, establishing processes to monitor and understand the impact of changes in global AI regulations, building flexible AI governance systems that can adapt across jurisdictions, and forming a framework of AI tool development that is adaptable to global regulatory flux. Executives should weigh global versus regional compliance strategies—balancing risk, cost, and speed to market. Companies should focus on developing auditable, explainable, and bias-mitigated AI systems to gain early regulatory trust. Stakeholder engagement—including proactive dialogue with regulators—will likely be critical to anticipating future guidance and reducing downstream friction. While the path ahead is complex, it is navigable—especially for companies that treat regulation not as a barrier, but as a blueprint for market leadership, patient trust, and lasting innovation.

Regional deep dives

Regional AI regulations: Decoded for life sciences companies

Regional regulatory outlook: A global landscape in flux

While some countries are taking a nonstatutory approach, the European Union has made headlines by becoming the first to enshrine broad-based AI regulation into law. The EU AI Act, which officially became a law in August 2024, has an implementation gradual rollout till August 2027 and represents the most sweeping statutory framework to date. In Japan, the first "AI Law," titled the Act on Promotion of Research and Development, and Utilization of AI-related Technology, was passed in May 2025 and represents an initial step in AI governance rather than a comprehensive regulatory framework. It is primarily a policy-driven initiative designed to foster innovation, advance research and development, and promote responsible use of AI technologies. The Act seeks to establish a foundation for AI governance. The current framework is light-touch and flexible, allowing room for future adjustments and stricter regulations as needed. In contrast, China balances agile regulation with state control and other major markets—including the United States, United Kingdom, and India—are relying on a mix of nonbinding guidance, sector-specific rules, or fragmented agency-led oversight. This divergence has created a complex landscape for life sciences companies to navigate. Table 1 provides a high-level summary of all jurisdictions discussed in this paper.

The variation in regulatory approaches, maturity, enforcement mechanisms, and risk classifications across the six jurisdictions we highlight presents operational and strategic challenges for global life sciences companies. The duality and tension are real: balancing AI-enabled innovation with growing and diverse scrutiny, while avoiding the risks of fragmented compliance strategies. From the EU's risk-based approach to Japan's human-centric and innovation-friendly AI guidelines to China's state-controlled data governance and the United States' executive order-driven approach, companies are being pulled in multiple directions simultaneously.

Yet across this complexity, a few key patterns are emerging. First, the six jurisdictions discussed in this paper—regardless of their enforcement structure—are aligning around shared values: privacy, data integrity, algorithmic transparency, and fairness.[25] Second, countries' AI regulatory approaches are evolving at different speeds and through different models: some through statutory law (EU), some have begun developing their legal framework for AI governance (Japan), others through nonstatutory and iterative regulatory sandboxes (India), agency-led frameworks (US, UK, China), or a mix of federal agency guidance and state statutory laws (US). Each of these approaches carries unique benefits and burdens, especially for life sciences companies operating cross-border with potential AI tools supporting clinical trials, post-market processes, or any regulated process.

To help life sciences leaders make sense of varied global approaches, this section of the paper offers focused summaries of regulatory developments in each of the six jurisdictions (EU, US, UK, China, Japan, and India) as well as for the global regulatory standard-setting organizations. For each, we explore statutory versus nonstatutory structures, areas of regulatory clarity and ambiguity, and key provisions affecting AI systems in development, deployment, and commercialization.

Moving forward

There is no single pathway through this evolving regulatory environment—but there are strategies that can help.

1. Duality needs to be managed in the face of change. Companies should closely monitor global AI regulatory evolving jurisdiction approaches, timelines, and enforcement milestones in each market. That can enable life sciences leaders to proactively navigate their company's approach to maintain compliance while pursuing the forefront of innovation.
2. Scalability, adaptability, and flexibility are the foundation to manage duality or innovation and risk. Life sciences leaders should look to implement governance systems that are flexible and scalable and capable of adapting to multiple compliance frameworks without duplicating effort.
3. Building a global market approach is critical. Companies should decide whether to design AI systems to the highest common denominator (e.g., EU standards) for global defensibility or pursue regional tailoring that optimizes local innovation.

This paper not only provides a regional overview but can also serve as a guide to help navigate this moment of transition. Life sciences companies that invest now in regulatory readiness, cross-functional collaboration, and strategic foresight may not only be better positioned to stay compliant - they could possibly lead the next generation of AI-enabled health innovation.

European Union: A statutory pioneer: Setting a global benchmark for AI regulation

The EU has taken a statutory approach to AI governance, cemented by the passage of the EU Artificial Intelligence Act—the first comprehensive AI law of its kind globally (table 2).26 The EU AI Act was formally adopted in 2024 and began phased implementation on August 1 of that year. Implementation will last till August 2027 when the regulation for high-risk systems comes into effect (figure 2 depicts the EU AI Act rollout timeline). It uses a risk-based classification system, segmenting AI systems into four categories: unacceptable risk, high risk, limited risk, and minimal risk.27 High-risk systems—especially those used in diagnostics, clinical trials, and patient monitoring—are subject to strict regulatory scrutiny.[28]

Life sciences applications are particularly affected under the "high-risk" classification. Any AI system that informs patient treatment or is embedded within a medical device must undergo rigorous validation, risk assessment, documentation, and ongoing monitoring to comply with the regulation.

Complementing the risk-based approach on application level, the EU AI Act is specifically looking on the provider side in the next stop of the rollout by regulating General-Purpose AI (GPAI), which went into effect August 2, 2025. A GPAI Code of Practice, published in July 2025, was prepared by large tech providers to provide guidance on how to fulfill the requirements.[29] The EU AI Act offers harmonized criteria across all member states and addresses AI models that are not application-specific but rather foundational in nature.[30]

To supplement the Act, the European Medicines Agency (EMA) has released a "Reflection paper on the use of artificial intelligence in the medicinal product lifecycle"[31] (figure 3), providing nonbinding but influential guidance across development, production, submission, and post-market processes. In its continuous effort to provide regulatory clarity, the EMA has published a first draft of EU GMP Annex 22, which will provide the binding regulatory framework for the use of AI in GxP-critical environments with direct impact on patient safety, product quality, or data integrity.[32]

The pro-innovation mechanisms, such as the AI regulatory sandboxes[33] and phased rollout timelines to assist companies in adapting AI literacy overviews,[34] support the deployment of the EU regulations, which are the most prescriptive AI regulations globally. They put high standards on ethical alignment, algorithmic transparency, and bias mitigation, reflecting a strong commitment to risk minimization and integrity. The EU AI Act might be seen by some jurisdictions as a blueprint, but for others it might be viewed as slowing down the innovation it seeks to shape.[35] Overall, the EU's AI regulatory trajectory sets a high bar for statutory oversight, particularly in life sciences—placing it firmly on the risk-averse end of the global regulatory spectrum.

Table 2: AI guidelines/regulations by jurisdiction—EU

Title	Effective date	Classification	Source link	Summary
EU AI Act	2024-08-01	Regulation	EU AI Act	The EU AI Act marks the first establishment of a comprehensive regulatory framework for AI across industries with specific chapters for the life sciences industry.
General-Purpose AI Code of Practice [EU AI Act]	2024-11-14	Guidance	The General-Purpose AI Code of Practice | Shaping Europe's digital future	The General-Purpose AI Code of Practice guides tech providers of large AI models in complying with the AI Act throughout the model lifecycle.
AI system definition [EU AI Act]	2025-02-02	Guidance	Guidelines on AI system definition to facilitate the first AI Act's rules application	The guidelines clarify what constitutes an AI system, helping providers and stakeholders determine whether their software falls under AI regulations for effective rule application.
Living repository of AI literacy practices [EU AI Act]	2025-02-02	Guidance	Living repository to foster learning and exchange on AI literacy	This article provides guidance on fulfilling the AI literacy requirements for staff and anyone using the AI systems.
Guidance on prohibited AI [EU AI Act]	2025-02-02	Guidance	Guidelines on prohibited AI practices, as defined by the AI Act	The guidelines specify prohibited AI practices—such as harmful manipulation, social scoring, and real-time remote biometric identification—within the AI Act's risk-based framework to safeguard health, safety, and fundamental rights.
Harmonised Standards for the European AI Act [EU AI Act]	2025-08-02	Guidance	Harmonised Standards for the European AI Act	These standards establish technical specifications and procedures to ensure AI systems comply with the AI Act's requirements for safety, transparency, and accountability.
EU AI Act [Remaining articles to be effective 2026–2027]	2026-08-02	Regulation	Regulation - EU - 2024/1689 - EN - EUR-Lex	The remainder of the AI Act starts to apply, except for some high-risk AI systems with specific qualifications.
	2027-08-02	Regulation		Regulation for high-risk systems comes into effect. All systems, without exception, must meet obligations of the AI Act. (Extended compliance deadline for high-risk AI systems already placed on the market before the Act enters into force.)

Title	Effective date	Classification	Source link	Summary
Overview of all AI Act National Implementation Plans	2025-08	Guidance	Overview of all AI Act National Implementation Plans | EU Artificial Intelligence Act	EU member states must designate national authorities responsible for enforcing the AI Act—such as market surveillance and notifying public authorities—through local laws by August 2025.
Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle	2024-09	Guidance	Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle	This paper details regulatory guardrails for the use of AI at each stage of the medicinal product lifecycle. This guidance provides the EU life sciences industry with clear expectations for compliance, safety, and ethical considerations when integrating AI into product development, evaluation, and monitoring.
EU GMP Chapter 4 and Annex 11	Draft for consultation 2025-07	Regulation (under consultation)	Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22 - European Commission	As part of the general update of EU GMP Chapter 4 and Annex 11, AI specifics were added, such as sole accountability of AI-generated records with the regulated user and the requirement for reference in the Quality Management System.
EU GMP Annex 22	Draft for consultation 2025-07	Regulation (under consultation)	EU GMP Annex 22	Annex 22 focuses on the use of AI with direct impact on patient safety, product quality, and data integrity. In the current draft, only the use of deterministic AI is allowed for the use in these highly critical GxP areas; therefore, detailed guidance is given on data management, explainability testing, and operations.

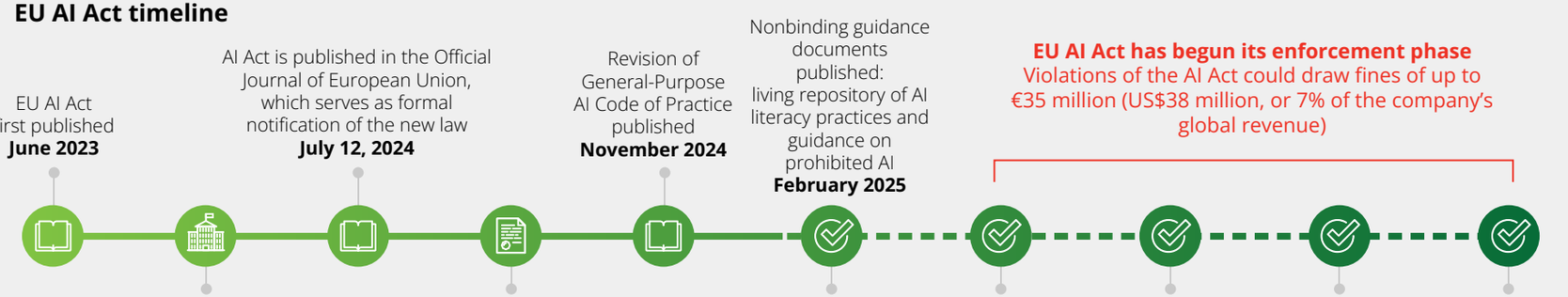
Figure 2: EU AI Act

Definition, timeline, and key tenets

Definition aligns with the OECD definition

An AI system is "a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments."

EU AI Act timeline



*High-risk systems must undergo third-party conformity assessment

Key tenets of EU AI Act

Human-centric and trustworthy AI

- Emphasis on safe, ethical AI
- Principles focus on governance, robustness, transparency, security, data quality ecology, and responsibility
- Risk-based approach

Risk clarification framework

- Unacceptable risk: Banned systems
- High risk: Requires conformity assessment
- Limited risk: Transparency obligations
- Minimal risk: Voluntary codes of conduct

Oversight structure

- European AI officer coordinate efforts
- National AI Supervisory Authorities in each member state

Scope and applicability

- Applies to AI system affecting EU citizens
- Specific exceptions for certain areas

Compliance requirements for high-risk system

- Conformity assessment before market placement
- Maintain detailed records and reporting

General Purpose AI (GPAI)

- Code of practice for GPAI
- Harmonized standards for compliance

Guidance documents

- Living repository of AI literacy practices
- Guidance on prohibited AI

Figure 3: EU reflection paper

The reflection paper provides consideration on the use of artificial intelligence (AI)/machine learning (ML) in the lifecycle of medicinal products (September 11, 2024)

1 **Drug discovery**
AI-driven predictions, such as drug-target interactions, should be experimentally validated before being used to support regulatory submissions. If results will be used as part of the total body of evidence, the data needs to be part of a regulatory review.

2 **Non-clinical development**
Iterative data-driven AI/ML approach should be followed, including prospective model performance testing during development. Applications that affect patient safety that are potentially relevant for assessment of the benefit-risk balance of a medicinal product, or have high regulatory impact in another manner, should be developed and tested accordingly.

3 **Clinical trials**
AI used in clinical trials (e.g., for patient recruitment, protocol design, or monitoring) must be documented in Clinical Trial Applications (CTAs); AI-assisted decisions should be justifiable and transparent to regulatory authorities. If the systems are part of the decision-making and statistical analysis, all models must be frozen during the operations, and incremental learning is prohibited.

4 **Precision medicine**
AI/ML models must be validated through clinical trials and real-world evidence. These models should be transparent and interpretable, with comprehensive documentation to facilitate regulatory review. Continuous monitoring and post-market surveillance are essential to maintain model performance and address any adverse events. Additionally, patient data must be handled in compliance with GDPR, ensuring privacy and informed consent, while actively mitigating biases.

5 **Product information**
Applications used for drafting, compiling, editing, translating, tailoring, or reviewing medicinal product information documents should be used under close human supervision and review.

6 **Manufacturing**
The reflection paper states that AI applications in pharmaceutical manufacturing must adhere to Good Manufacturing Practice (GMP) requirements; continuous monitoring is required to ensure AI maintains high-quality standards in production processes.

7 **Post-authorization phase**
The reflection paper indicates that AI-driven tools used in safety monitoring and pharmacovigilance should be benchmarked against existing methods to ensure reliability; European Medicines Agency (EMA) requires that any AI-based safety monitoring tool be documented in risk management plans (RMPs) but can be more flexible.

General considerations

- The RP provides considerations on the use of AI and ML in the lifecycle of medicinal products
- The RP is complementary (vertical guidance) to the EU AI Act (horizontal regulations).

Reflection paper: General considerations

1. The reflection paper provides considerations on the use of AI and ML in the lifecycle of medicinal products.
2. The reflection paper is complementary (vertical guidance) to the EU AI Act (horizontal regulations).
    - **A risk-based approach** for development, deployment, and performance monitoring of AI and ML tools.
    - The **level of scrutiny depends on the level of risk** and regulatory impact posed by the system.
    - The **marketing authorization applicant or holder is responsible** to ensure that all algorithms, models, data sets, and data processing pipelines used are fit for purpose and are aligned with ethical, technical, scientific, and regulatory standards as described in GxP standards and current European Medicine Agencies (EMA) scientific guidelines.
    - It's critical to **identify aspects of AI/ML that would fall within the remit of EMA or the Member States National Competent Authorities** as the level of scrutiny into data assessment will depend on this remit.
        - **Medical devices with AI/ML technology** can be used within the context of clinical trials to generate evidence in support of a marketing authorization application and/or can be combined with the use of a medicinal product. In such cases, EMA will be involved in the assessment.
        - Similarly, if a **device is used to provide recommendations in the Summary of Product Characteristics**, e.g., on monitoring, EMA will be involved in the assessment.
    - Organizations must **address data quality, bias mitigation, and explainability** while aligning AI governance across regulatory, clinical, and information technology (IT) functions to prevent compliance gaps. Establishing standardized validation, documentation, and oversight mechanisms, including an AI Governance Committee, will be essential for ensuring regulatory adherence and responsible AI deployment.

United States: Innovation-first, regulator-led

The United States has adopted a nonstatutory, agency-led approach to AI regulation, with oversight dispersed across a network of federal and state entities including the FDA, HHS, National Institutes of Health (NIH), and Federal Trade Commission (FTC) (Table 3, Figure 4 and 5). This approach has become more dynamic with a renewed prioritization and emphasis on AI innovation-led dominance (table 3).[36]

The US regulatory posture shifted significantly with Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence," issued on January 23, 2025.[37] This EO revoked EO 14110 (issued by the previous administration), emphasizing the removal of regulatory obstacles that could hinder innovation. It directed federal agencies to reassess and revise AI-related regulations and policies within 180 days, aiming to align government AI actions with the goal of sustained global leadership. An interagency task force, headed by the director of the Office of Management and Budget (OMB) who will convene a Chief AI Officer Council, was created to oversee the development of a national AI roadmap.[38]

While federal legislation remains absent, the FDA has pushed ahead with domain-specific guidelines such as the AI/ML Software as a Medical Device (SaMD) Action Plan.[39] This plan outlines pre- and post-market pathways for AI applications in diagnostics, drug monitoring, and clinical support systems.[40] Complementing these efforts, the FDA is implementing an agency-wide AI integration initiative across all 14 centers, aimed at improving review efficiency and reducing bottlenecks.[41] A key milestone in this initiative was the launch of Elsa, the FDA's first AI tool, in June 2025, which has been deployed agency-wide to assist FDA staff by automating time-consuming and repetitive administrative tasks. The FDA has stated that Elsa will not make any final regulatory decisions on approvals; rather, it will help accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets.[42]

In parallel, the FTC has focused on AI in consumer protection contexts, including enforcement against misleading claims in AI-driven health tools. NIST continues to play a central role through its voluntary AI Risk Management Framework (RMF) and broader standards work on trustworthy AI.[43]

AI policy in the US also varies at the state level. More than 550 AI-related bills have been introduced across 45 states and Puerto Rico,[44] with California and Colorado leading in early regulatory experimentation.[45] However, these state-level efforts may be redefined based on the federal roadmap under EO 14179.[46]

On the global stage, the administration has articulated its innovation-first stance in international forums, including the 2025 AI Action Summit in France.[47] The US declined to sign a multilateral AI risk agreement,[48] instead committing to $700 billion in AI investment and emphasizing a domestically led, ideologically neutral AI infrastructure.[49]

The United States currently sits on the innovation-heavy end of the global AI spectrum, while NIST's AI RMF offer structure,[50] the absence of a centralized federal AI statute, and the evolving federal policy environment place a premium on agility and interagency coordination.

For life sciences companies, this creates a dual imperative: to interpret evolving federal guidance while also navigating diverse state regulations.[51] While the current regulatory environment allows for flexibility in innovation, it also introduces uncertainty—requiring companies to stay engaged in policy developments and maintain adaptable compliance systems.[52]

Table 3: AI guidelines/regulations by jurisdiction—US

Government body/agency	Title	Effective date	Classification	Source link	Summary
States	**Colorado AI Act**	2026-02	Regulation	Consumer Protections for Artificial Intelligence | Colorado General Assembly	The Act requires a developer of a high-risk artificial intelligence system to use reasonable care to protect consumers from any known or reasonably foreseeable risks of algorithmic discrimination in the high-risk system. When effective, this will be the first US law to regulate the development and use of high-risk AI systems.
States	**Artificial Intelligence 2024 and 2025 legislation**	N/A	Database	Artificial Intelligence 2025 Legislation Artificial Intelligence 2024 Legislation	2024 and 2025 tracking database.
White House	**Executive Order (EO) 14179 and OMB Memoranda M-25-21 and M-25-22**	2025-01	Executive Order	Executive Order 14179 Removing Barriers to American Leadership in Artificial Intelligence Driving Efficient Acquisition of Artificial Intelligence in Government	Revokes certain existing AI policies and directives (EO 14110: "Safe, Secure, and Trustworthy Development and Use of AI") that act as barriers to American AI innovation, clearing a path for the US to act decisively to retain global AI leadership. It directs that, within 180 days, the heads of agencies develop an action plan for how to achieve the EO policy change.
FDA	**Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP Are Working Together**	2025-02	Guidance	OMP CDER AI Discussion Paper	The February 2025 update streamlines the FDA's AI agenda around four priorities: (1) collaborative public-health safeguards, (2) AI-friendly regulations, (3) lifecycle standards and best practices, and (4) research to evaluate and monitor AI performance.
FDA	**Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**	2025-01	Guidance	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products | FDA	This guidance provides recommendations on the use of AI to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU).

Government body/agency	Title	Effective date	Classification	Source link	Summary
FDA	**Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations**	2025-01	Guidance	Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations | FDA	This guidance includes an emphasis on the total product lifecycle approach (TPLA) for AI-enabled devices, calling for comprehensive risk management by conducting risk assessments; continual performance validation; and transparent, bias-aware labeling, user interface, and cybersecurity controls.
FDA	**Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions**	2024-12	Guidance	Marketing Submission Recommendations for a PCCP for Artificial Intelligence-Enabled Device Software Functions	This guidance includes the Predetermined Change Control Plan (PCCP) framework that permits iterative improvements to AI-enabled devices, specifies appropriate submission types, and recommends PCCP information in device labeling to enhance transparency and clarify device performance and safety.
FDA	**Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles**	2024-06	Guidance	Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles | FDA	This guidance refines the 2021 good machine learning practice (GMLP) principles framework by detailing stronger transparency principles, especially around model logic, for ML-enabled medical devices.
HHS	**HHS AI Use Case Inventory**	2024	Guidance	HHS AI Use Cases AI Use Cases Inventory | HHS.gov	HHS aims to continue managing an AI use-case inventory that was originally initiated through White House EO 13960. This inventory is a centralized repository of non-classified AI use cases from US federal agencies.

Government body/agency	Title	Effective date	Classification	Source link	Summary
FDA	**Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles**	2023-10	Guidance	Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles | FDA	This guidance provides recommendations on the use of AI to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU).
NIH	**Artificial intelligence activities at the NIH and relevant policies** **Artificial Intelligence in Research: Policy Considerations and Guidance**	2024/5	Site Hub Guidance	NIH – Artificial Intelligence NIH – Artificial Intelligence – Policy considerations	This comprehensive framework guides the ethical use of AI in biomedical research, emphasizing transparency and accountability. It promotes inclusivity and diversity in AI data sets and research teams to ensure fairness, mitigate biases, and address potential biases in AI algorithms to ensure equitable outcomes.
NIH	**NIH Data Management and Sharing Policy**	2023	Guidance	Data Management & Sharing Policy Overview	Promotes biomedical research discovery by promoting the sharing, validation, accessibility, and reuse of scientific data.
CDC	**Artificial Intelligence and Machine Learning: Applying Advanced Tools for Public Health**	2025	AI CDC Hub	CDC's Vision for Using Artificial Intelligence in Public Health	CDC's Data Modernization Initiative supports AI, ML, and other powerful solutions for large or complex data. These solutions can help us maximize insights from data and systems and use those insights to drive public health action.

Figure 4: US AI regulatory landscape

The regulatory governance for artificial intelligence (AI) in the United States is characterized by a multifaceted agency approach

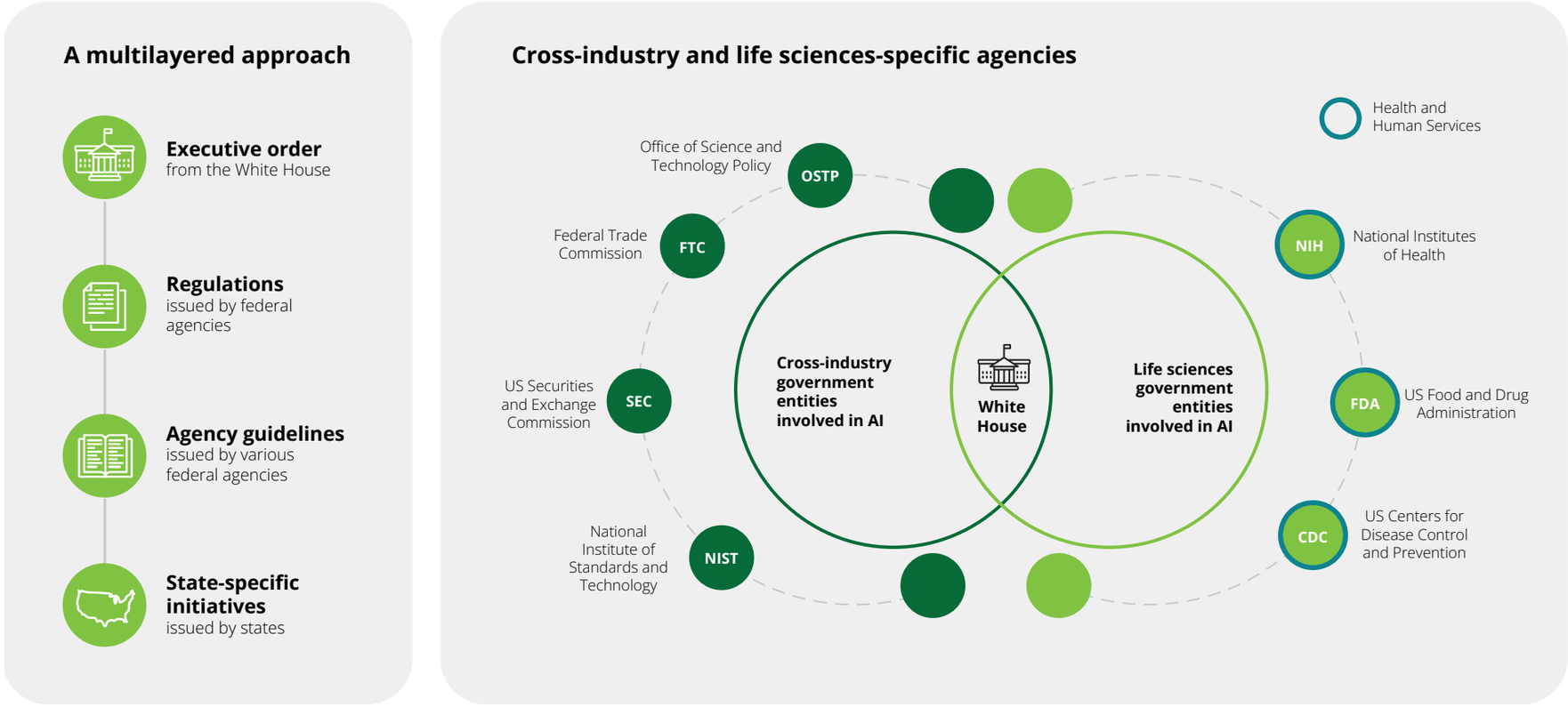
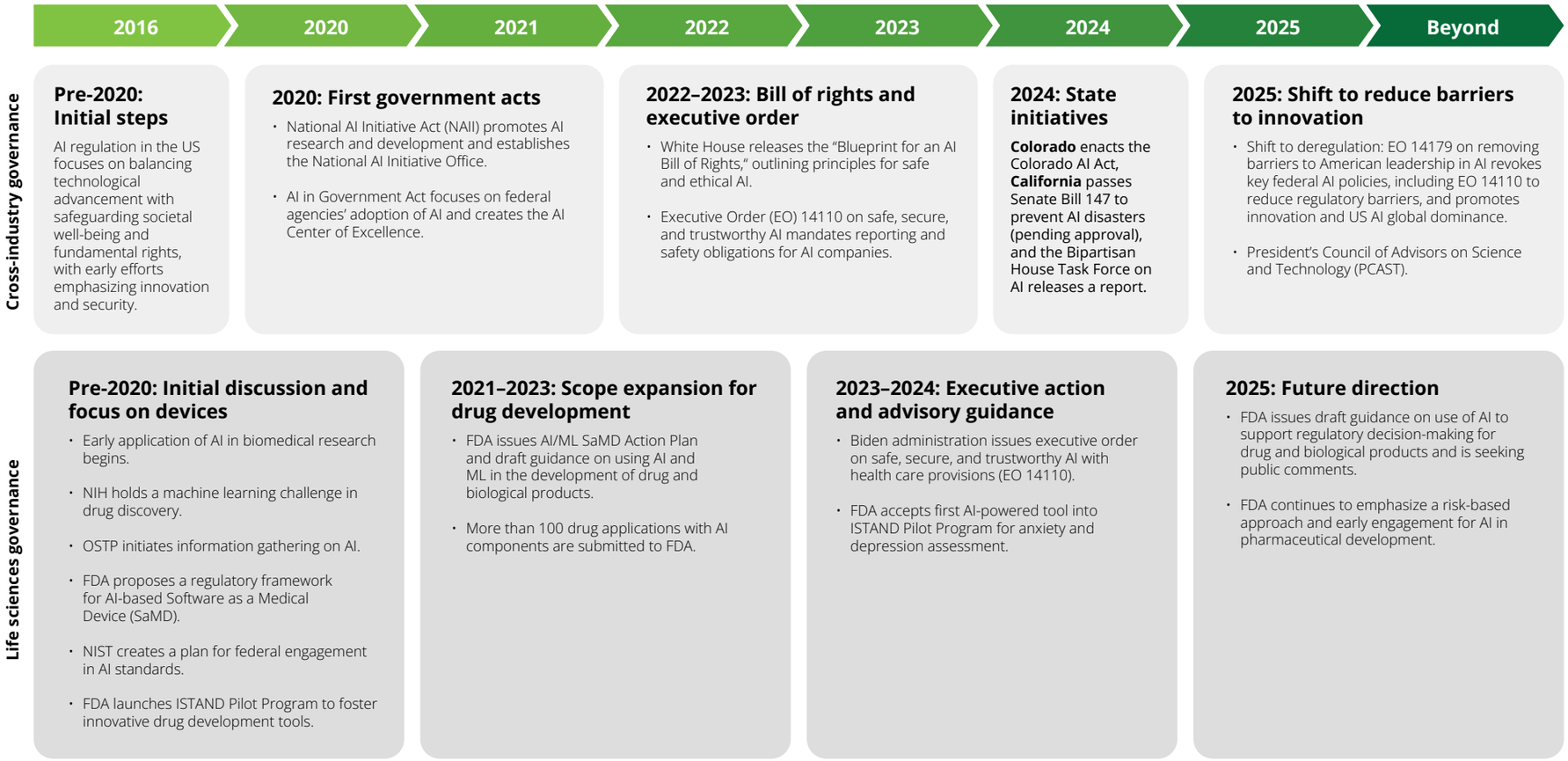


Figure 5: US AI regulatory timeline

Evolution of US AI governance



United Kingdom: Sector-guided, innovation-driven

The United Kingdom (UK) has taken a nonstatutory, sector-guided approach to AI regulation, emphasizing flexibility, innovation, and proportionality (table 4).[53] The UK's overarching AI regulatory strategy, defined in its 2023 AI Regulation and Governance Framework (figure 6), sets out five cross-sectoral principles: safety, transparency, fairness, accountability, and contestability.[54] These principles are being operationalized through regulatory guidance issued by authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Information Commissioner's Office (ICO), and the Competition and Markets Authority (CMA). For the life sciences sector, the MHRA has played a pivotal role in shaping the UK's regulatory landscape. In April 2024, the agency published its approach to regulating AI, including a commitment to regulate AI across three dimensions: as a medical device (AIaMD), as a regulator using AI internally, and as a tool used by companies to generate regulatory evidence.[55] These principles are aligned with the UK government's overall vision for responsible AI innovation. Several relevant legislative and non-legislative measures affect the UK life sciences AI ecosystem. These include the Data Protection and Digital Information (DPDI) Bill, the Digital Markets, Competition and Consumers Act, and the Clinical Trials Regulation.[56] Though not specific to AI, these regulations shape the compliance landscape for systems processing sensitive health and personal data.

The UK government continues to support innovation through tools such as regulatory sandboxes. Notably, in May 2024, the MHRA launched the "AI Airlock"—a sandbox program for AI medical devices, developed in partnership with National Health Service (NHS) England and other stakeholders.[57] The initiative allows companies to test AI-driven medical products in a controlled environment, helping developers and regulators identify risks and streamline compliance.[58] The pilot phase concluded in April 2025, and a detailed report is expected to be published in fall 2025. Initial insights include the identification of significant regulatory gaps regarding AI-generated synthetic data and AI validation of generated data, and that retrieval-augmented generation (RAG)-based techniques could be utilized to help mitigate AI safety concerns.[59]

Complementing these efforts, the NHS Transformation Directorate has released detailed guidance for AI developers and adopters,[60] while the UK government's AI Playbook, launched in February 2025, outlines procurement and deployment principles for public-sector use of AI (figure 7).[61] Though targeted at government bodies, this playbook offers best practices that life sciences companies can adapt for private-sector compliance.

From a policy standpoint, the UK remains committed to evolving its AI governance framework. The government has announced plans to develop statutory regulations for high-capability foundational models and to place the AI Safety Institute on a formal legal footing.[62] A new Regulatory Innovation Office (RIO), established in October 2024, further supports these ambitions by reducing regulatory barriers and accelerating the adoption of transformative technologies in health care.[63]

On the risk-innovation spectrum, the UK continues to lean toward innovation, offering a permissive but principle-based framework.[64] However, its approach is expected to mature as it formalizes legal structures and as harmonization advances globally. The UK's agile, regulator-led approach enables life sciences companies to innovate within a framework of evolving regulations, anticipating more definitive future legislation.

Table 4: AI guidelines/regulations by jurisdiction—UK

Title	Effective date	Classification	Source link	Summary
UK's AI Playbook	2025-02	Guidance	AI Playbook for the UK Government	This playbook provides comprehensive guidance for public-sector organizations on the safe and effective use of AI. It includes principles and best practices for selecting, procuring, and deploying AI technologies, emphasizing ethical considerations and risk management.
UK's Framework on AI	2024-02-06	Guidance	A pro-innovation approach to AI regulation: government response The UK's framework for AI regulation | Deloitte UK	This guidance outlines a cross-sector, outcome-based, non-statutory framework on AI regulation, emphasizing characteristics such as adaptivity and autonomy. This approach leverages existing laws and sector-specific expertise to manage AI applications effectively, aiming to balance innovation with safety and ethical considerations.
Public Authority Algorithmic and Automated Decision-Making Systems Bill	Announced: 2024-09-09 Effective date: To be determined	Regulation	Public Authority Algorithmic and Automated Decision-Making Systems Bill	The bill obliges public authorities to complete Algorithmic Impact Assessments and keep Algorithmic Transparency Records before deploying automated decision-making systems—embedding transparency and accountability in government AI use. Although public-sector focused, it sets a benchmark likely to influence oversight expectations in life sciences and other industries.
Medicines and Healthcare products Regulatory Agency (MHRA) Regulatory Strategy	2024-04	Guidance	MHRA's AI regulatory strategy ensures patient safety and industry innovation into 2030	The strategy focuses on proportionate regulation of AI, ensuring that innovative products can be developed and deployed safely without unnecessary regulatory burdens. It aligns with the government's four key AI principles: safety, security, and robustness; appropriate transparency and explainability; fairness, accountability, and governance; and contestability and redress.
AI Airlock	2024-05	Tool	AI Airlock: The regulatory sandbox for AIaMD	A regulatory sandbox designed to address challenges in regulating AIaMDs. This initiative allows developers to test and refine their AI medical devices in a controlled environment, facilitating collaboration between regulators, industry experts, and the NHS.

Figure 6: UK AI five core principles framework

UK nonstatutory cross-sector and outcome-based AI framework (February 6, 2024)

UK AI definition	**No formal definition, outcomes-based approach, focused on two defining characteristics that will guide sectoral interpretations** 1. Adaptivity - The ability of AI systems to see patterns and make decisions in ways not directly envisioned by human programmers. 2. Autonomy - The capacity of AI systems to operate, take actions, or make decisions without the express intent or oversight of a human.
Three types of AI systems	**Highly capable general-purpose AI** Foundational models that can perform a wide variety of tasks (novice to superhuman capabilities that match or exceed today's most advanced models). **Highly capable, narrow AI** Foundational models that can perform a narrow set of tasks, normally within a specific field (superhuman capabilities that match or exceed today's most advanced models). **Agentic AI or AI agents** Emerging subset of AI that competently completes multiple steps over long time frames.

Three core pillars underpinning five core principles

Safety, security, and robustness

Appropriate transparency and explainability

Fairness

Accountability and governance

Contestability and redress

Leverage existing regulatory authorities and frameworks

Establish central function to facilitate effective risk monitoring and regulatory coordination

Support innovation by piloting a multi-agency advisory service—AI and digital hub

UK AI framework general considerations

The framework:
- The UK government has adopted a **cross-sector and outcome-based framework** for regulating AI, **underpinned by five core principles**.

The framework goal:
- To **balance innovation and safety** by applying the existing technology-neutral regulatory framework to AI.

Implementation:
- Regulators will **implement the framework in their sectors/domains by applying existing laws and issuing supplementary regulatory guidance**.

Safety and transparency:
- **Voluntary safety and transparency measures** for developers of highly capable AI models and systems will also supplement the framework and the activities of individual regulators.

Statutory:
- The framework will **not be codified into law for now**, but the government anticipates the need for targeted legislative interventions in the future.

Future:
- Organizations must **prepare for increased AI regulatory activity** over the next year, including guidelines, information gathering, and enforcement. International firms will inevitably have to navigate regulatory divergence.

Figure 7: UK AI Playbook

Artificial Intelligence Playbook for the UK Government (January 2025)

Playbook objective

"The AI Playbook will support the public sector in better understanding what AI can and cannot do, and how to mitigate the risks it brings. It will help ensure that AI technologies are deployed in responsible and beneficial ways, safeguarding the security, wellbeing, and trust of the public we serve."

1

Know what AI is and what its limitations are

- AI is a rapidly evolving field with potential and risks, necessitating a thorough understanding of its capabilities and limitations.
- It is crucial to use AI responsibly, enhance its accuracy, and implement rigorous testing processes.

2

Use AI lawfully, ethically, and responsibly

- Carefully consider legal, ethical, and data protection issues to ensure responsible use and adherence to regulations.
- Address potential biases, ethical concerns, and environmental impacts throughout the AI development lifecycle.

3

Know how to use AI securely

- AI systems face unique security threats like data poisoning and hallucinations, as well as amplifying generic risks such as phishing and cyberattacks.
- Mitigate risks and implement safeguards, technical controls, security testing, content filtering, and validation checks to ensure accuracy and data protection.

4

Have meaningful human control at the right stage

- Monitor AI behavior and prevent harmful effects on users, ensuring human validation for high-risk decisions and meaningful intervention strategies.
- Ensure human control during development and deployment, test the product pre- and post-deployment, and incorporate user feedback.

5

Understand how to manage the AI lifecycle

- Understand AI product lifecycle, from tool selection, setup, maintenance, and updates, to ensuring security.
- Monitor and mitigate potential issues like drift, bias, and hallucinations.
- Employ robust testing and monitoring.
- Adhere to the Technology Code of Practice.

6

Use the right tool for the job

- Determine if AI is the best solution for your needs, as sometimes traditional technologies may be more effective.
- When implementing AI, select the appropriate deployment patterns and models, and refer to resources on identifying suitable use cases.

7

Be open and collaborative

- Leverage cross-government communities for collaboration.
- Engage with other departments, civil society, and the public, while adhering to the Algorithmic Transparency Recording Standard (ATRS), documenting AI use in decision-making, and ensuring transparency and societal benefits of AI.

8

Work with commercial colleagues from the start

- Seek early advice from commercial
- colleagues to understand AI's implications and ensure alignment with commercial requirements.
- Collaborate with them to maintain consistent expectations for responsible and ethical AI use.

9

Have skills and expertise needed to implement and use AI

- Understand and implement technical and ethical requirements for AI use.
- Equip team with the skills to use, design, build, and maintain AI solutions.
- Decision-makers and policy professionals should understand AI's risks and opportunities.

10

Use these principles with your organization's policies and have the right assurance in place

- The 10 playbook principles provide a consistent approach for the UK government to use AI tools.
- Users must also adhere to their organization's specific policies.
- Understand, monitor, and mitigate AI-related risks by engaging assurance teams early, documenting review and escalation processes, and establishing an AI review board or program-level board.

China: Agile, statutory, and state-controlled

China has pursued a statutory, state-led approach to AI regulation, characterized by rapid legislative and policy activity designed to align AI development with national priorities (table 5).[65] Since 2023, the country has introduced and expanded several laws targeting data security, algorithmic governance, and AI system accountability across sectors, including life sciences.[66]

In May 2024, a draft Artificial Intelligence Law was proposed by legal scholars, representing a foundational step toward a unified AI regulatory code.[67] If passed, this legislation would formalize risk-based classification of AI systems and impose legal obligations on developers and deployers of high-risk AI, including those used in clinical trials, diagnostics, and patient care.[68] These obligations focus on data traceability, transparency, and compliance with cybersecurity and public safety standards.[69]

China's regulatory oversight is executed through several authorities. The National Medical Products Administration (NMPA) has issued guidelines regulating AI-assisted medical devices, emphasizing clinical validation, algorithmic explainability, and lifecycle monitoring.[70] It maintains audit rights over AI-enabled systems used in medical applications.[71]

Additionally, AI in health care is governed by broader data-related statutes such as the Personal Information Protection Law (PIPL)[72] and the Data Security Law (DSL),[73] which together mandate strict controls over patient data use, storage, and cross-border transfer—issues central to life sciences operations.[74]

While China does not currently offer formal sandbox mechanisms, its regulatory model is highly responsive. Policymakers can enact regulations or revisions swiftly in response to emerging technologies or perceived risks.[75] This agile structure allows regulators to continuously refine their oversight and respond to developments in AI innovation while maintaining control over strategic sectors.

On the innovation-risk spectrum, China falls on the state-control-heavy end, with high regulatory oversight and centralized enforcement designed to protect national interests.[76] Though this may offer some predictability for companies operating in the life sciences space, it also requires rigorous compliance procedures and close monitoring of regulatory shifts.[77]

Recent developments highlight China's commitment to asserting leadership in AI by 2030, while ensuring that AI deployment supports state objectives and adheres to ethical principles, national security priorities, and public welfare standards.[78]

Table 5: AI guidelines/regulations by jurisdiction—China

Title	Effective date	Classification	Source link	Summary
Regulations on the Management of Artificial Intelligence Assisted Diagnosis Technology	2017-12-31	Regulation	Regulations on the Management of Artificial Intelligence Assisted Diagnosis Technology	The regulations set standards for the development, application, and oversight of AI-assisted diagnostic technologies. They outline basic requirements for product quality control, clinical validation, registration, and training.
Regulations on the Management of Artificial Intelligence Assisted Treatment Technology	2017-12-31	Regulation	Regulations on the Management of Artificial Intelligence Assisted Treatment Technology	The regulations set standards for AI-assisted treatment technologies used in medical settings. They address safety, clinical validation, product registration, data privacy, training, and other critical considerations.
Guiding Principles for the Classification of AI Medical Software Products	2021-07-01	Guidance	Guiding Principles for the Classification of AI Medical Software Products	The principles classify AI medical software as medical devices according to data type, core functionality, and intended medical use. They also outline compliance risks and penalties for unregistered AI medical devices, including confiscation of illegal gains, seizure of unregistered devices and equipment, fines, and suspension of business operations.
Administrative Provisions on Algorithm Recommendation for Internet Information Services	2022-03-01	Regulation	Administrative Provisions on Algorithm Recommendation for Internet Information Services	The provisions set standards for providers of information services and introduce specific regulations for algorithmic recommendations.
Guidelines for the Registration and Review of Artificial Intelligence Medical Devices	2022-03-07	Guidance	Guidelines for the Registration and Review of Artificial Intelligence Medical Devices	The guidelines require high data quality, algorithm transparency, performance evaluation, and strong risk management for AI medical devices. Applicants must submit technical documentation on algorithms, data sources, validation results, and clinical applicability to ensure compliance.

Title	Effective date	Classification	Source link	Summary
Administrative Provisions on Deep Synthesis of Internet-based Information Services	2023-01-10	Regulation	Administrative Provisions on Deep Synthesis of Internet-based Information Services	These provisions strengthen oversight of deep synthesis technologies in internet information services and establish regulatory standards for their use within China.
Provisional Measures for the Administration of Generative Artificial Intelligence Services	2023-08-15	Regulation	Provisional Measures for the Administration of Generative Artificial Intelligence Services	These measures promote the responsible development and regulation of GenAI services, aiming to safeguard national security, public interests, and the rights of individuals and organizations.
Guidelines for Clinical Evaluation and Registration Review of AI-Assisted Detected Medical Devices	2023-11-07	Guidance	Guidelines for the Clinical Evaluation and Registration Review of AI-Assisted Detected Medical Devices	The guidelines require manufacturers of AI-assisted detected medical devices to complete pre-market registration, submit technical documentation, and undergo National Medical Products Administration (NMPA) review, focusing on algorithm interpretability, data compliance, and clinical validation to ensure safety and efficacy.
Cybersecurity Technology – Basic Security Requirements for Generative Artificial Intelligence Service	2025-11-01	Guidance	National Standard: Cybersecurity Technology – Basic Security Requirements for Generative Artificial Intelligence Service	This guidance defines basic security requirements for GenAI services, covering corpus and model security, security measures, and guidelines for conducting security assessments.
Cybersecurity Technology—Labeling Method for Content Generated by Artificial Intelligence	2025-09-01	Regulation	China's AI-Labeling Measures and Mandatory National Standards Take Effect September 1 | Loeb & Loeb LLP Cybersecurity Technology—Labeling Method for Content Generated by Artificial Intelligence	This regulation requires explicit labeling of AI-generated content by service providers and users, and mandates that distribution platforms verify labeling practices and disclosure of AI services.

India: Adaptive and entrepreneurial

India's approach to AI regulation remains adaptive and sector-driven. As of the time of this writing, there is no comprehensive statutory framework governing AI in India. Instead, oversight is shaped by a mix of government strategies, nonbinding guidelines, and sector-specific rules—particularly in health care and life sciences (table 6).[79] The regulatory environment is primarily informed by foundational documents such as the "National Strategy for Artificial Intelligence" (2018) by NITI Aayog[80] and the 2021 "Principles for Responsible AI,"[81] which lay out ethical standards including safety, inclusivity, privacy, and accountability. These principles align with international best practices, positioning India for global collaboration in AI governance.[82]

In January 2025, the Ministry of Electronics and Information Technology (MeitY) released the AI governance guidelines report, which advocates for a whole-of-government regulatory approach. Key recommendations include creating a technical secretariat, developing an AI incident database, encouraging voluntary commitments, and mandating risk mitigation strategies. These guidelines aim to ensure that AI development is ethical, transparent, and secure while preventing fragmented governance across sectors.[83]

The Indian Council of Medical Research (ICMR) is also expected to issue new standards for AI-enabled medical devices, with an emphasis on clinical validation and algorithmic accountability.[84] Additionally, the draft Digital Personal Data Protection Rules (2023)[85] introduces data security and consent obligations for AI systems processing personal health data, including mandatory Data Protection Impact Assessments for significant data fiduciaries.

India's AI policy is further bolstered by the IndiaAI Mission, launched in 2024,[86] and the creation of the IndiaAI Safety Institute in 2025.[87] These initiatives promote innovation, responsible AI practices, and digital infrastructure development, particularly in collaboration with academia, startups, and the public sector.[88]

Overall, India maintains a nonstatutory, innovation-forward posture while laying the groundwork for structured AI governance. Life sciences companies operating in India need to navigate a dynamic regulatory environment that offers both flexibility and emerging compliance obligations across data privacy, ethics, and health-specific AI use cases.[89]

Table 6: AI guidelines/regulations by jurisdiction—India

Title	Effective date	Classification	Source link	Summary
Digital India Act (Upcoming)	To be determined	Regulation	The AI Regulatory Landscape in India: What to Know	This regulation is set to replace the Information Technology Act of 2000, introducing AI-specific provisions related to algorithmic accountability, consumer rights, and regulatory oversight.
AI Governance Framework and Guidelines	2025-01	Guidance	AI Governance Framework and Guidelines by MeitY	This report outlines a comprehensive strategy for regulating AI. It emphasizes a "whole-of-government" approach, advocating for inter-ministerial collaboration to efficiently oversee AI developments, exchange information, and create unified policy frameworks.
Digital Personal Data Protection Rules	2025-01	Guidance	Digital Personal Data Protection Rules, 2025	This provides guidelines for implementing DPDPA. These rules specify conditions for obtaining verifiable consent to process personal data, including sensitive health information used in AI algorithms.
Digital Personal Data Protection Act (DPDPA)	2023	Regulation	The Digital Personal Data Protection Act	The Indian government has introduced sector-specific guidelines to regulate AI applications pertinent to their domains. DPDPA sets a technology-agnostic framework that grants individuals enforceable data rights, obliges "data fiduciaries" to process personal data lawfully, permits regulated cross-border transfers, and imposes steep monetary penalties for noncompliance.
Principles of Responsible AI	2021	Guidance	Ai_for_All_2022.pdf	These principles outline AI ethical standards such as safety, inclusivity, privacy, and accountability. It serves as a foundational framework for organizations developing or deploying AI systems, emphasizing the consideration of ethical implications throughout the AI lifecycle.
National Strategy for Artificial Intelligence	2018	Guidance	National Strategy for Artificial Intelligence	This strategy emphasizes the adoption of AI in key sectors such as health care, agriculture, education, smart cities, and smart mobility. It also highlights the importance of research and development, workforce upskilling, and establishment of infrastructure to support AI innovation.

Japan: Gradual shift from guidelines to structured oversight

Japan's regulatory approach to AI has historically relied on nonbinding "soft law" guidelines (table 7).[90] However, in 2025, Japan made significant progress toward more structured oversight. On May 28, 2025, Japan's National Diet (Japan's legislative body) passed the Act on Promotion of Research and Development, and Utilization of AI-related Technology, commonly referred to as the Japan AI Act.[91] This Act marks Japan's first AI law. It calls for government-led policy development and regulatory alignment with global standards, signaling a shift toward formal statutory governance.[92] The Act establishes a national framework to advance the research, development, and ethical use of AI, prioritizing transparency, international collaboration, and human-centric principles. It governs AI applications to prevent misuse, such as privacy violations and copyright infringements, while fostering innovation and enhancing competitiveness. The Act ensures AI contributes to societal well-being, drives economic growth, and remains adaptable to emerging risks through ongoing evaluation and strategic policy enhancements.

While the Japan AI Act lays the policy foundation for AI governance at the national level, Japan's regulators continue to use the "soft law" guideline approach by issuing a series of guidelines that provide a practical, voluntary framework for companies to adopt ethical AI practices, such as the *AI guidelines for business*. Released in April 2025 by the Ministry of Internal Affairs and Communications (MIC) and the Ministry of Economy, Trade and Industry (METI), these guidelines target AI developers, providers, and users across sectors. They outline 10 principles for responsible AI implementation, including human-centric design, transparency, fairness, privacy protection, and accountability. While voluntary, the guidelines provide structured best practices that align with international standards and are increasingly being adopted across industries, including life sciences.[93]

In addition, the industry alliance also issued guidelines encouraging all parties to voluntarily adopt them, such as the *Generative AI utilization guide for health care providers*. Published in January 2024 by the Japan Digital Health Alliance (JaDHA),[94] this sector-specific guidance supports responsible adoption of AI in health care. It emphasizes data privacy, clinical accuracy, and ethical use, targeting hospitals, pharmaceutical companies, and research institutions.[95]

Japan is also preparing for reforms to the Act on the Protection of Personal Information (APPI). A proposed revision by the Personal Information Protection Commission (PPC), released in February 2025, introduces exceptions to consent requirements in certain statistical use cases and aims to clarify data protection obligations related to AI.[96]

Japan's position on the innovation-risk spectrum remains moderate, balancing a pro-innovation stance with evolving oversight. The AI Act and expanding guidance indicate a gradual shift toward firmer regulatory control, particularly for high-risk applications in health care, clinical trials, and diagnostics.

Table 7: AI guidelines/regulations by jurisdiction—Japan

Title	Effective date	Classification	Source link	Summary
Act on Promotion of Research and Development, and Utilization of AI-related Technology (AI Act)	Approval date: 2025-05-28 Effective date: 2025-09-01	Regulation	2025-Promotion of Research, Development and Utilization of AI-related Technologies	The Act on Promotion of Research and Development, and Utilization of AI-related Technology is Japan's first AI law. The AI Act requires companies to cooperate with the government on AI and requires the government to develop AI guidelines aligned to global standards.
Amendment of Act on the Protection of Personal Information (APPI)	Effective date: 2022-04-01	Regulation	APPI	The amendment released in April 2022 indirectly affects AI by regulating personal data use, requiring developers and organizations to ensure compliance, transparency in AI models, and ethical practices to prevent misuse of personal information. The Personal Information Protection Commission (PPC) has announced plans to amend the Act in 2025. Further amendments are expected to address emerging challenges in data protection, which may encompass issues related to AI.
AI Guidelines for Business Ver. 1.1	2025-04-04	Guidance	Version 1.1 – AI Guidelines for Business	These guidelines unify policies from the Ministry of Internal Affairs and Communications (MIC) and the Ministry of Economy, Trade and Industry (METI), incorporating global trends and the Hiroshima AI Process.[97] They provide practical, nonbinding direction on responsible AI adoption—covering compliance, risk management, and societal benefit—for developers, providers, and users across all industries, including life sciences.
Generative AI Utilization Guide for Health Care Providers	2024-01-18	Guideline	Gen AI Utilization Guide for HCP	This voluntary guideline is for businesses in the health care sector that offer services utilizing AI. It offers practical advice on maintaining data privacy, ensuring accuracy, and upholding ethical standards in AI adoption.

Global standards organizations: Toward harmonization

The global AI regulatory landscape remains disparate (table 8 and figure 8), with no unified governance system in place. Instead, a handful of influential organizations and international bodies are advancing parallel frameworks aimed at improving alignment and interoperability—each with distinct priorities and approaches. For life sciences companies operating across borders, navigating the variety of regulatory approaches presents both a compliance challenge and a strategic opportunity.

Efforts to promote global harmonization have gained momentum, particularly around shared values such as ethical AI use, data privacy, human rights, and system safety. However, meaningful alignment has yet to emerge. Countries continue to adopt varying levels of statutory and non-statutory approaches to AI regulation, which complicates the development of universally applicable compliance guidance and standards.

Several global organizations are shaping the direction of international AI standards:

- **ISO/IEC JTC 1/SC 42:** Formed in 2017, this joint technical committee has become a hub for AI standardization.[98] To date, it has published 34 standards and has 42 more in development, including 12 in 2024 and one in 2025.[99] These cover areas such as AI terminology, ethical design principles, data integrity, and transparency. In October 2024, ISO, the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU) announced a joint effort to host the 2025 International AI Standards Summit in Seoul.[100]
- **NIST:** NIST released its AI RMF in 2023 and launched a global engagement plan (AI 100-5) in 2024.[101] The framework emphasizes risk mapping and mitigation for AI systems, including specialized profiles such as the NIST AI-600-1 for AI.[102] In 2025, NIST also issued guidance on adversarial ML in its AI 100-2 report,[103] detailing attack mitigation strategies to promote secure AI operations.
- **IEEE:** The Institute of Electrical and Electronics Engineers (IEEE) currently manages 15 AI standards in active approval and 23 in draft development.[104] These standards address algorithmic transparency, data privacy, and model safety. In May 2025, IEEE hosted its inaugural International Conference on AI Industry Standard and Quality Assurance in Santa Clara, California, which was focused on AI implementation in regulated sectors including life sciences.
- **ISPE/GAMP:** The International Society for Pharmaceutical Engineering (ISPE) incorporated AI/ML considerations into its GAMP 5 guidance in July 2022.[105] Appendix D11 provides detailed implementation and validation protocols for AI systems used in pharmaceutical manufacturing.
- **IMDRF:** In January 2025, the International Medical Device Regulators Forum (IMDRF) released its "Good machine learning practice for medical device development" principles.[106] These principles emphasize continuous improvement, international cooperation, and safe AI integration in health care technologies.
- **WHO:** The World Health Organization's AI guidance has matured significantly since its 2021 ethical principles.[107] The 2024 update offers more than 40 recommendations covering AI, large language models (LLMs), and large multi-modal models (LMMs), with an emphasis on clinical safety, cybersecurity, and misinformation mitigation.[108] A new WHO Collaborating Centre on AI for health governance at Delft University of Technology in the Netherlands is advancing this agenda globally.[109]
- **G20, GPAI,[110] and bilateral initiatives:** Multinational forums such as the GPAI and G20 are also contributing to the conversation. The 2024 G20 Rio Declaration underscored ethical and inclusive AI development,[111] while the India-France Declaration on AI (February 2025) emphasized bilateral cooperation in research and governance.[112] GPAI is currently working with 44 countries to promote the responsible development and use of AI.

Although these frameworks have commonalities, such as promoting fairness, transparency, and data protection, a global regulatory consensus remains elusive. Life sciences companies navigating this evolving space should consider aligning early with internationally recognized standards to stay ahead of compliance expectations. Adoption of these emerging guidelines can help mitigate regulatory risk, reduce market entry barriers, and demonstrate leadership in responsible AI deployment.

Table 8: AI guidelines/regulations by jurisdiction: Global organizations focusing on AI standards

Title	Effective date	Classification	Source link	Summary
ISO/IEC 5259-1 Part 1: Overview, terminology, and examples	2024-07	Guideline	ISO/IEC 5259-1:2024	Part 1 focuses on data quality for analytics and ML. This standard provides an overview, terminology, and illustrative examples to help organizations understand and apply the entire series effectively. It establishes the framework for assessing and enhancing data quality across different phases of the data lifecycle, which is crucial for reliable analytics and ML outcomes.
ISO/IEC 5259-2 Part 2: Data quality measures	2024-11	Guideline	ISO/IEC 5259-2:2024	Part 2 defines a data quality model and a set of measurable characteristics to help organizations assess and report on data quality in the context of analytics and ML. It builds on existing standards (such as ISO/IEC 25012 and ISO 8000) and provides a common foundation for ensuring that data used in AI and analytics processes is trustworthy and fit for purpose.
ISO/IEC 5259-3 Part 3: Data quality management requirements and guidelines	2024-07	Guidance	ISO/IEC 5259-3:2024	Part 3 defines the requirements and guidance for managing the quality of data used in analytics and ML. It provides a flexible framework for setting up a data quality management system (DQMS) that can adapt to various AI lifecycles, ensuring that the data powering ML systems is reliable, auditable, and aligned with stakeholder expectations.
ISO/IEC 5259-4 Part 4: Data quality process framework	2024-07	Guideline	ISO/IEC 5259-4:2024	Part 4 defines a standardized process framework to manage data quality in analytics and ML. It provides guidance for organizations to implement reliable, structured approaches across different ML types—including supervised, unsupervised, semi-supervised, and reinforcement learning—with a particular focus on data labeling, evaluation, and lifecycle management.
ISO/IEC 5339 Guidance for AI applications	2024-01	Guideline	ISO/IEC 5339:2024	ISO/IEC 5339 provides guidance on AI applications, emphasizing stakeholder engagement and the AI application lifecycle. It aims to enhance multi-stakeholder communication and acceptance by offering a framework that includes the make, use, and impact perspectives of AI systems.

Title	Effective date	Classification	Source link	Summary
ISO/IEC 5392 Reference architecture of knowledge engineering	2024-03	Guideline	ISO/IEC 5392:2024	This document defines a reference architecture of knowledge engineering (KE) in AI. The reference architecture describes KE roles, activities, constructional layers, components, and their relationships among themselves and other systems from systemic user and functional views.
ISO/IEC TR 5469 Functional safety and AI systems	2024-01	Guideline	ISO/IEC TR 5469:2024	This document describes the properties, related risk factors, available methods, and processes relating to: (1) use of AI inside a safety-related function to realize the functionality; (2) use of non-AI safety-related functions to ensure safety for AI-controlled equipment; and (3) use of AI systems to design and develop safety-related functions.
ISO/IEC TS 8200 Controllability of automated artificial intelligence systems	2024-04	Guideline	ISO/IEC TS 8200:2024	This document specifies a basic framework with principles, characteristics, and approaches for the realization and enhancement of automated AI systems' controllability. This document is applicable to all types of organizations developing and using AI systems during their whole lifecycle.
ISO/IEC TS 12791 Treatment of unwanted bias in classification and regression machine learning tasks	2024-10	Guidance	ISO/IEC TS 12791:2024	This document describes how to address unwanted bias in AI systems that use ML to conduct classification and regression tasks. It provides mitigation techniques that can be applied throughout the AI system lifecycle in order to treat unwanted bias.
ISO/IEC TR 17903 Overview of machine learning computing devices	2024-05	Guideline	ISO/IEC TR 17903:2024	This document surveys ML computing devices, including the following: (1) ML computing device terminology and characteristics; and (2) existing approaches to the setting and use of characteristics for optimizing ML computing device performance.
ISO/IEC TR 24030 Use cases	2024-04	Guideline	ISO/IEC TR 24030:2024	This document provides a collection of AI use cases across various domains. It encompasses an extensive range of applications, illustrating the applicability and potential of AI in different sectors and contributing significantly to the field of AI standardization.

Title	Effective date	Classification	Source link	Summary
ISO/IEC TS 25058 Systems and software Quality Requirements and Evaluation (SQuaRE) — Guidance for quality evaluation of AI systems	2024-01	Guideline	ISO/IEC TS 25058:2024	This document provides guidance for the evaluation of AI systems using an AI system quality model.
ISO/IEC 5259-5 Data quality for analytics and machine learning (ML)	2025-02	Guideline	ISO/IEC 5259-5:2025	Part 5 provides a governance framework to help organizations oversee and direct data quality for analytics and ML. It equips governing bodies with strategic tools to ensure that data quality measures are implemented effectively across all levels of the organization and throughout the entire data lifecycle.
ISO/IEC TR 20226 Environmental sustainability aspects of AI systems	2025-07	Guideline	ISO/IEC TR 20226:2025	This document provides an overview of the environmental sustainability aspects (e.g., workload, resource and asset utilization, carbon impact, pollution, waste, transportation, location) of AI systems during their lifecycle and related potential metrics.
ISO/IEC 42005 AI system impact assessment	2025-05	Guideline	ISO/IEC 42005:2025	This document provides guidance for organizations conducting AI system impact assessments. These assessments focus on understanding how AI systems—and their foreseeable applications—may affect individuals, groups, or society at large. The standard supports transparency, accountability, and trust in AI by helping organizations identify, evaluate, and document potential impacts throughout the AI system lifecycle.
ISO/IEC 42006 Requirements for bodies providing audit and certification of artificial intelligence management systems	2025-07	Guidance	ISO/IEC 42006:2025	This document sets out the additional requirements for bodies that audit and certify AI management systems (AIMS) according to ISO/IEC 42001. It builds on ISO/IEC 17021-1 and ensures that certification bodies operate with the competence and rigor necessary to assess organizations developing, deploying, or offering AI systems.
A Plan for Global Engagement on AI Standards	2024-07	Guideline	NIST AI 100-5	NIST announced this plan to align its AI Risk Management Framework (RMF) with international standards and regulations to better map, measure, and manage AI use cases.

Title	Effective date	Classification	Source link	Summary
Artificial Intelligence Risk Management Framework: Generative Artificial Intelligence Profile	2024-07	Guideline	NIST-AI-600-1	This document outlines several risks associated with GenAI. These include the potential for AI to automate cyberattacks, generate disinformation, and engage in social engineering. The draft highlights the dual-use nature of GenAI technologies—powerful tools that can drive innovation and present significant risks if not properly managed.
Adversarial Machine Learning: A Taxonomy and Terminology of Attacks and Mitigations	2024-01	Guideline	NIST AI 100-2	This report provides guidance on identifying, addressing, and managing risks associated with adversarial ML to ensure the secure and resilient operation of AI systems.
IEEE Recommended Practice for the Evaluation of AI Dialogue System Capabilities	2025-03-28	Guideline	IEEE Std 3128-2025	This provides a framework for the intelligence capabilities of AI dialogue systems such as chatbots, consulting terminals, or operation interfaces, which is established in this recommended practice. The recommended practice classifies the intelligence capabilities of an AI dialogue system into three categories—cognitive intelligence, emotional intelligence, and system completeness.
IEEE Standard for Algorithmic Bias Considerations	2025-01-24	Guideline	IEEE 7003-2024	The processes and methodologies to help users address issues of bias in the creation of algorithms are described in this standard.
IEEE Guide for Framework for Trustworthy Federated Machine Learning	2024-12-19	Guidance	IEEE 3187-2024	In this standard, a general view of framework for trustworthy federated ML is provided in four parts: a principle in trustworthy federated ML, requirements from the perspective of different principles and different federated ML participants, and methods to realize trustworthy federated ML.
IEEE Standard Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification Portable Avatar Format (MPAI-PAF)	2024-12-06	Guideline	IEEE 3306-2024	This standard adopts MPAI Technical Specification Version 1 as an IEEE Standard. It defines: (1) file formats so recipients can decode and display avatars exactly as sent; (2) an AI module that turns text plus "personal status" cues into a portable avatar; and (3) an AI framework that links these modules—and data from other MPAI specs—for avatar-based video conferencing.

Title	Effective date	Classification	Source link	Summary
IEEE Standard Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification MPAI Metaverse Model (MMM) Architecture	2024-11-27	Guideline	IEEE 3305-2024	This standard adopts MPAI Technical Specification Version 1 as an IEEE Standard. The Technical Specification MPAI Metaverse Model (MMM) Architecture specifies terms and definitions, operation models, functional requirements of processes, etc.
IEEE Standard Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification Multimodal Conversation – Ver. 2	2024-11-14	Guideline	IEEE 3300-2024	This standard adopts MPAI Technical Specification Version 2 as an IEEE Standard. Multimodal Conversation (MPAI-MMC) specifies use cases, all of which share the use of AI to enable a complete and intense form of human-machine conversation.
IEEE Standard Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification Artificial Intelligence Framework (AIF) – Ver. 2	2024-11-14	Guideline	IEEE 3301-2024	This standard adopts the MPAI AI Framework (MPAI-AIF) Technical Specification Version 2 as an IEEE Standard. The MPAI-AIF Technical Specification specifies architecture, interfaces, protocols, and application programming interfaces of an AI Framework (AIF), especially designed for the execution of AI-based implementation, but also suitable for mixed AI and traditional data processing workflow.
IEEE Guide for Collecting and Managing Transmission Line Inspection and Maintenance Data	2024-09-09	Guidance	IEEE 1808-2024	A high-level overview is provided in this guide for key principles and considerations learned through experience that help ensure common pitfalls are avoided and enhance the usability of systems and collected data.

Title	Effective date	Classification	Source link	Summary
IEEE Guide for an Architectural Framework for Explainable Artificial Intelligence	2024-08-30	Guideline	IEEE 2894-2024	This guide provides a technological framework that aims to increase trustworthiness of AI systems using explainable artificial intelligence (XAI) technologies and methods. The document also provides measurable solutions to evaluate AI systems in terms of explainability.
IEEE Standard for Robustness Evaluation Test Methods for a Natural Language Processing Service That Uses Machine Learning	2024-08-09	Guideline	IEEE 3168-2024	This standard specifies test methods for evaluating the robustness of a natural language processing (NLP) service that uses machine learning.
IEEE Standard Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification Connected Autonomous Vehicle-Architecture	2024-07-12	Guideline	IEEE 3307-2024	This technical specification specifies the architecture of a connected autonomous vehicle (CAV) based on a reference model. The CAV is broken down into subsystems for each as follows: functions, input/output data, and topology of components.
IEEE Recommended Practice for the Application of Knowledge Graphs for Talent Services	2024-07-05	Guidance	IEEE 3154-2024	This recommended practice assists developers in constructing knowledge graphs in the field of talent services more efficiently and consistently. In addition, it provides a general implementation method for institutions and enterprises to use knowledge graphs in different application scenarios, such as talent recruitment and development.

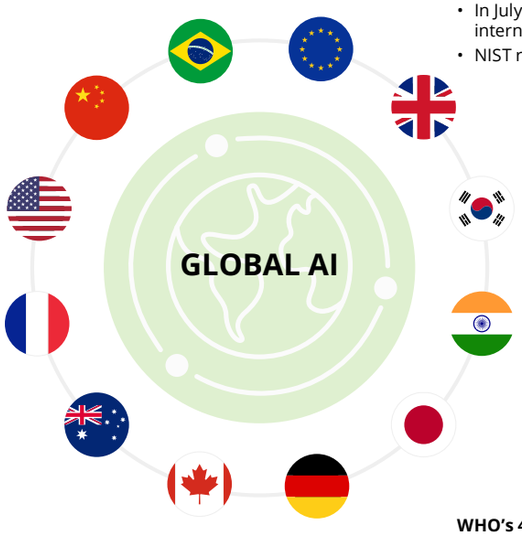
Title	Effective date	Classification	Source link	Summary
IEEE Standard for Ethical Considerations in Emulated Empathy in Autonomous and Intelligent Systems	2024-06-28	Guideline	IEEE 7014-2024	Guidance and actions for the ethical development, deployment, or decommission of autonomous and intelligent systems that attempt to emulate aspects of human empathy are provided by this standard.
IEEE Standard for Adoption of Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI) Technical Specification Neural Network Watermarking (NNW) V1	2024-02-12	Guideline	IEEE 3304-2023	This is an adoption of the Moving Picture, Audio and Data Coding by Artificial Intelligence (MPAI)—Technical Specification Neural Network Watermarking as an IEEE Standard.
IEEE Standard for Blockchain-Based Hepatobiliary Disease Data Extraction and Exchange	2024-01-26	Guideline	IEEE 3806-2023	This standard specifies the blockchain-based system architecture, interfaces, protocols, testing, and verification for the extraction and exchange of hepatobiliary disease data across multiple organizations and stakeholders.
IEEE Recommended Practice for Improving Generalizability of Artificial Intelligence for Medical Imaging	2025-07-11	Guideline	IEEE Std 3350-2025	The contents of this recommended practice delineate an architecture and offer suggestions for enhancing the generalizability of AI models in medical imaging.

Title	Effective date	Classification	Source link	Summary
IEEE Standard for Data Access Management for Identity Relationships	2025-07-10	Guidance	IEEE Std 3812.2-2025	This standard provides a comprehensive framework for managing such relationships and managing application data access using identity relationships, emphasizing data interoperability, security, and regulatory compliance. By establishing clear protocols for data access, privacy, and integration with third-party utilities, the standard aims to provide accurate, secure, and transparent handling of identity relationships and the flow of data between different identity relationships.
IEEE Standard for Computer Vision (CV)—Technical Requirements for Algorithms Application Programming Interfaces (APIs) of Deep Learning Framework	2025-05-29	Guideline	IEEE Std 3110-2025	Functional and technical requirements for the interfaces between algorithms and learning frameworks (including the interfaces provided by training frameworks), and between algorithms and data sets in the development of AI computer vision algorithms, are specified in this standard.
IEEE Standard for Evaluation Method of Machine Learning Fairness	2025-05-26	Guideline	IEEE Std 3198-2025	A method for evaluating the fairness of machine learning is specified in this standard. Multiple causes contribute to the unfairness of machine learning. These causes of ML unfairness are categorized. The widely recognized and used definitions of ML fairness are presented. Various metrics corresponding to the definitions and how to calculate the metrics are specified in this standard. Detailed conditions and procedures to set up the tests for evaluating ML fairness are given by the test cases in this document.
IEEE Standard for the Procurement of Artificial Intelligence and Automated Decision Systems	2025-05-23	Guideline	IEEE Std 3119-2025	This standard helps procurement teams reduce risks in artificial intelligence systems (AIS) by using tailored risk management practices when purchasing AIS. Specific process steps for AIS problem definition, solicitation preparation, vendor and solution evaluation, contract negotiation, and contract monitoring are described.
GAMP 5 – A Risk-Based Approach to Compliant GxP Computerized Systems, Second Edition	2022-07	Guideline	GAMP 5	The International Society for Pharmaceutical Engineering (ISPE) has updated GAMP 5 to include specific guidance on AI and ML in Appendix D11. This appendix offers detailed guidance on implementing and validating AI/ML systems in pharmaceutical manufacturing, ensuring regulatory compliance, and maintaining product quality and safety.

Title	Effective date	Classification	Source link	Summary
Good Machine Learning Practice for Medical Device Development: Guiding Principles	2025-01	Guidance	IMDRF Working Groups on AI/ML Enabled Medical Devices	This is a comprehensive framework for the responsible development and deployment of AI technologies in medical devices. By promoting safety, effectiveness, international collaboration, and continuous improvement, these principles support the advancement of AI medical devices and contribute to improved patient outcomes worldwide.
Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models	2025-03-25	Guideline	WHO Guidance – 2024	The 2024 update expands on the foundational principles with more than 40 recommendations for AI in clinical care, administration, education, and research. It also highlights new risks such as misinformation, bias, and cybersecurity, emphasizing the need for stronger policies and global collaboration to ensure safe and ethical AI adoption in health care.
India-France Declaration on Artificial Intelligence	2025-02-12	Guideline	India-France Declaration on Artificial Intelligence	This document focuses on bilateral cooperation in AI research, development, and innovation. It emphasizes ethical AI use, promoting transparency, fairness, and privacy, and aims to foster joint research, expertise exchange, and AI applications for global challenges like health and climate change.
G20 Rio de Janeiro Leaders' Declaration	2024-11	Guideline	G20 Rio de Janeiro Leaders' Declaration	This declaration emphasizes ethical, responsible, and inclusive AI development, highlighting fairness, transparency, data protection, and international cooperation. It advocates for bridging digital divides, ensuring safe AI, and promoting digital inclusion, with initiatives for workplace AI guidelines and international governance discussions.
AI and the G20: Striking a balance between innovation and governance	2024-11	Guideline	Stal - AI and the G20 Striking a balance between innovation and governance.pdf	This paper urges the G20 to craft a single, inclusive framework that promotes ethical, responsible, and innovative AI, positioning the bloc to set global standards while addressing societal challenges.

Figure 8: Global AI landscape

Global entities involved in AI regulatory frameworks, international cooperation, and providing contributions to global AI standards



ISO/IEC and ITU unite to pioneer AI standards

- In 2024, JTC 1/SC 42, formed by ISO and IEC, published 12 standards, with 33 total published and 36 more in development.
- In January 2025, ISO/IEC joins forces with ITU to launch the 2025 International AI Standards summit to address global AI challenges.

NIST's efforts in leading AI risk management

- In July 2024, NIST initiated its NIST AI 100-5 to align its AI Risk Management Framework with international standards and regulations.
- NIST released the NIST-AI-600-1 to help organizations manage unique risks posed by Generative AI.

IEEE advancing AI/ML standards and inaugural conference

- As of January 2024, IEEE has 14 standards in the "Active-Approve" phase and 19 standards in the "Active-Draft" phase to address AI/ML aspects on data privacy, algorithmic transparency, and safety protocols.
- In May 2025, IEEE held its inaugural IEEE Conference on AI Industry Standard Development and Quality Assurance in Santa Clara, California.

GAMP 5 update on AI implementation and validation

- ISPE has updated GAMP 5 to include AI/ML-specific guidance in Appendix D11 titled "Artificial Intelligence and Machine Learning (AI/ML)."
- This guidance focuses on implementing and validating AI/ML systems to ensure regulatory compliance, product quality, and patient safety.

IMDRF's Framework for Responsible AI

- In January 2025, IMDRF published its "Good Machine Learning Practice for Medical Device Development: Guiding Principles."
- GMLP provides a comprehensive framework for the responsible development and deployment of AI technologies in medical devices to promote safety, effectiveness, international collaboration, and continuous improvement.

WHO's 40 recommendations for AI use in health

- In 2024, WHO's update expanded on its broad ethical principles on AI use in health to more than 40 recommendations in areas of Generative AI, LLMs, and LMMs.
- These recommendations cover AI use in clinical care, administration, education, and research, as well as the risks of AI usage, such as misinformation, bias, and cybersecurity, to ensure safe/ethical AI use.

G20/GPAI developments in championing inclusive AI use

- The G20 Rio de Janeiro Leaders' Declaration (November 2024) emphasized ethical, responsible, and inclusive AI development, highlighting fairness, transparency, data protection, and international cooperation.
- GPAI is currently working with 44 countries to promote the responsible development and use of artificial intelligence.

Common themes across regulations

- Ethical AI
- Data privacy
- Safety and security
- Human rights
- Balance between regulation and innovation

Challenges in AI regulations

- Global harmonization
- Compliance
- Innovation vs. regulation

ISO: International Organization for Standardization
IEC :International Electrotechnical Commission
ITU: International Telecommunication Union
IEEE: Institute of Electrical and Electronics Engineers
JTC 1/SC 42: The Joint Technical Committee 1/Subcommittee 42
ISPE: International Society for Pharmaceutical Engineering
IMDRF: International Medical Device Regulators Forum
WHO: World Health Organization
LLMs: Large Language Models
LMMs: Large multi-modal models
GPAI: The Global Partnership on Artificial Intelligence

Use cases: Summary

Navigating global AI compliance in life sciences applications through two use cases for AI systems is not embedded directly in the product

As global medicinal product (MP) and medical device (MD) companies adopt AI to support the product lifecycle, they face a rising layer of complexity: jurisdiction-specific AI compliance. These companies typically customize their products to meet local regulatory requirements. However, when AI is integrated into product development, clinical trials, post-market surveillance, or complaint handling, companies must now also consider how each market governs the use of AI—even when the AI system is not embedded directly in the product.

The evolving global AI regulatory environment introduces significant challenges. With no harmonized international standard for life sciences AI regulation, organizations have to choose one of two options:

- **A global-first strategy** that adheres to the most stringent market regulations, ensuring universal defensibility but potentially limiting innovation.
- **A regional/local strategy** that tailors AI deployment to individual market requirements, which supports agility but adds operational complexity.

Companies also face a strategic decision on timing:

- **Wait for regulatory clarity**, risking market agility, limiting or delaying cost savings measures, which may lead to reputational and market-share adverse impacts.
- **Advance AI development and deployment**, gaining a competitive edge but exposing themselves to compliance risks, increased costs, and potential market rollbacks.

The following use-case examples illustrate the potential challenges and regulatory considerations associated with deploying AI across the six key jurisdictions (EU, US, UK, China, India, and Japan) and what several global regulatory standards-setting organizations should consider as they define their standards. The analysis was conducted in general terms and doesn't represent a specific AI solution.

Use case A: AI-powered complaint handling for medical devices

AI can support complaint handling by automating intake, triage, proposed remediation, and escalation, when needed, to health authorities. This has the potential to help companies:

- Improve and standardize complaint categorization and risk assessment.
- Identify reportable complaints more efficiently and with a higher rate of compliance.
- Reduce manual effort and enhance regulatory response time.
- Reduce cost of quality and focus resources on value creation.

When evaluated across all jurisdictions we discuss in this paper, the use of AI in powering complaint handling raises considerations that might not be the same across all jurisdictions and might impact the AI tool being developed.

Global regulatory considerations:

- **EU:** Risk categorization under the AI Act may trigger conformity assessment and health authority registration requirements; EMA guidelines require validation and documentation—even for incremental learning models:
  - **EU AI Act:** Current phase of the legislative rollout only requires that the AI tool does not fall in the category of forbidden application. However, consideration should be in place to ensure compliance as AI Act implementation progresses through its timeline. Although unlikely, the AI tool needs to be evaluated if it falls under the category of "high-risk" applications, which would trigger a conformity assessment and a registration with the EU regulatory authority.
  - Due to the lack of explicit guidance for the use in the medical device sector, the principles and standards referenced in the MDR have to allow for the usage of software in the regulated environment. In addition, industry-agonistic standards for AI are used to demonstrate state-of-the-art development and governance of the application.
  - Self-learning systems are allowed, but the guidelines for trustworthy AI and human-in-the-loop should be followed.
- **US:** Define intended use clearly; extensive validation and monitoring are required; and a Predetermined Change Control Plan (PCCP) must address continuous updates:
  - **Defining regulatory scope** is important if the AI application is an administrative aid or its functionality classifies it as a software subject to Quality System Regulation (21 CFR Part 820).
  - **Validation and monitoring** ensure the model has "seen" all complaint nuances and the plan for continual refinement. To reduce potential biases, a big and representative data set should be used in the model.
  - **PCCP** needs to specify what changes are planned.
    - **Managing updates:** If the AI model is intended to be updated over time, determine whether to use a PCCP or not. Both pathways include significant challenges:
      - If PCCP, defining scope, modification, and impact assessment require significant effort.
      - If not PCCP, each update may require revalidation and potentially new regulatory submission.

- **UK:** Governed by proportionality and risk, AI must be explainable, fair, and privacy-compliant under the UK's General Data Protection Regulation (UK GDPR).
  - **Proportionality and risk considerations:** Under UK AI principles, the level of AI governance is assessed based on the risk.
  - **Oversight:** While automation is beneficial, human-in-the-loop processes are essential for reviewing edge-case complaints.
  - **Governance:** The organization must assign roles and responsibilities for AI decisions and ensure governance mechanisms are in place.
  - **Bias and fairness:** Historical complaints may contain biased outcomes. AI should be evaluated for fairness and an equitable decision-making process.
  - **Data privacy and protection:** Complaint data may include personal information subject to UK GDPR.
- **China:** Compliance with cybersecurity laws (classified protection of cyber security, or CPCS), Personal Information Protection Law (PIPL; China's data protection regulation), and cross-border data transfer (CBDT) is critical.
  - If the **system handles patient information**, it is likely to face CPCS requirements for security certification compliance, required by China's Public Security Bureau.
  - Consideration needs to be given to **meeting privacy compliance requirements** such as PIPL and CBDT if the complainant's personal information is captured or transferred cross-border.
- **India:** Digital Personal Data Protection Act (DPDPA) of 2023 governs data consent and usage, and ICMR/NITI Aayog principles guide AI ethics and explainability.
  - India currently lacks a dedicated AI regulatory framework, but some of the **considerations from DPDPA and guidelines issued by ICMR and NITI Aayog** would be applicable.
    - **ICMR Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare:** While these guidelines focus on ethical considerations in research and health care AI, they highlight important principles like data privacy, transparency, accountability, and safety, which are relevant to complaint management and protocol deviations.
- **Explainability and transparency of AI decisions** meets potential expectations (influenced by NITI Aayog principles and consumer rights) for explaining why the AI categorized a complaint or recommended a specific remediation, especially in case of disputes, which can be challenging with complex ML models ("black box" issue).
- **AI model validation uncertainty:** Lack of specific Indian regulatory guidelines (from relevant bodies like the Bureau of Indian Standards (BIS), consumer protection agencies, or sector regulators like the Central Drugs Standard Control Organization (CDSCO), if applicable, on how to validate the performance, accuracy, and fairness of AI algorithms used for complaint categorization and remediation recommendations creates compliance ambiguity.
- **Unclear AI error liability:** Current Indian laws lack clarity on liability if AI makes mistakes and the laws have an absence of AI-specific rules for complaint handling in regulated sectors.

- **Japan:** Covered by existing Good Vigilance Practice (GVP) and APPI laws, with an emphasis on validation, traceability, and human oversight.
  - While Japan does not have AI-specific regulations for complaint triage, any AI tool used in post-market safety management is subject to the same validation, documentation, and auditability requirements as traditional safety-related systems.
    - **Validation complexity:** When the AI-enabled complaint triage system indirectly affects post-market safety actions—for example, when AI helps with signal detections or case prioritizations—the system must be fully validated to ensure AI can accurately identify safety signals without causing any false positives/negatives.
    - **Traceability:** GVP regulations require that decisions must be traceable and records of the implementation of post-marketing safety management must be preserved. Detailed logs need to be kept for the classification and remediation recommendation generated by AI to ensure that they can be reviewed and verified when necessary.
    - **Preventing bias:** Appropriate measures should be taken to manage the quality of data, such as training data and data collection, to mitigate harmful bias.
    - **Strict patient data protection:** When using AI for complaint classification and remediation recommendation, especially when it involves patients' personal information, it's required to ensure that APPI privacy protection requirements are met. Medical device companies must take strict data protection measures to prevent data leakage or abuse. Medical device companies should also ensure that all data used for AI training is de-identified and does not include information that can directly identify an individual.
- **Global regulatory standard-setting organizations:** NIST, ISO, and GAMP frameworks recommend human-in-the-loop controls, audit trails, and data quality checks.
  - **Classification:** Assess the use case based on the design principles of autonomy and control. The use case may be classified as a high-risk AI system due to its direct impact on patients. (GAMP)
  - **Implement controls** to govern, map, measure, and monitor the AI development lifecycle. (NIST)
  - **Key controls** include data quality, privacy, unwanted bias, risk management, testing, and transparency. (NIST)
  - **Human in the loop:** If there is no human in the loop, it may be a restricted system (US + EU AI Act). Human-in-the-loop references the need for an additional review by a human that AI is assessing as intended.
  - **Preapproval registration vs. HA preapproval:** Article 49: Registration | EU Artificial Intelligence Act
    - **Privacy:** Any global deployment must account for privacy and data-related regulations and standards across various countries. (GDPR)
    - **Training and testing data:** Ensuring the availability of testing data across multiple demographics is essential. Significant effort is required to create contexts for the available data. (NIST)
    - **Documentation:** Comprehensive documentation, including audit logs and transparency, will be necessary. (7.5 of ISO 42001)

Use case B: AI-enabled clinical trial protocol deviation management

AI can support protocol deviation management by triaging events, assisting investigations, and suggesting corrective and preventive actions (CAPAs). Potential benefits include:

- Improved process standardization, consistency, and subjectivity in deviation classification and management;
- Accelerated process timelines and reduction of resourcing and cost; and
- Enhanced data integrity.

Global regulatory considerations:

- **EU:** Subject to EMA qualification and International Council for Harmonization (ICH) good clinical practice (GCP) guidance; incremental learning is prohibited; and high scrutiny of statistical contributions.
  - **EU AI Act:** Current phase of the legislative rollout only requires the AI tool does not fall in the category of forbidden application. However, consideration should be in place to ensure compliance as AI Act implementation progresses through its timeline. Although unlikely, the AI tool needs to be evaluated if it falls under the category "high-risk" applications, which would trigger a conformity assessment and a registration with the EU regulatory authority. Future integrity and validation requirements are expected to be already covered following the industry regulations:
  - EMA AI reflection paper is defined per area of application, in which specific rules should be followed for a machine learning application. In the clinical trial area, the guardrails are the strongest. If the system is considered to have high patient or regulatory risk, according to ICH E6 on GCP, the system may need to be qualified by the EMA and might have to be described in the GCP dossier:[113]
    - If not previously qualified, the full model architecture, logs from model development, validation and testing, training data, description of the data, and processing pipeline could be required for the trial protocol dossier and thus may be requested for comprehensive assessment at the time of market authorization, clinical trial application, or GCP inspection.
    - The system needs to be prospectively validated with prospectively generated data.
    - For applications included in the statistical analysis of clinical trials, additional aspects need to be considered like the prohibition of incremental learning.
  - EU GMP Annex 22 (Draft): It is expected that the application is classified as critical, meaning it has direct impact on product quality and patient safety; therefore, only deterministic models, not self-learning systems, are allowed.
    - A detailed and descriptive "Intended Use" must be provided, including characterization of data and responsibility of the operator (human-in-the-loop).
    - The development and usage is only allowed by qualified personnel.
    - Pre-defined test metrics and acceptance criteria have to be defined.
    - The acceptance criteria must be at least as high as the performance in place.
    - Test data must be independently verified and technically controlled, including controls on persons having access to the test data.
    - Explainability studies and confidence scoring are mandatory.
    - During operations, model change control, configuration management, monitoring, and human review are mandatory.

- **US:** Risk management and data integrity are critical; PCCP must define retraining scope and validation across multiple AI functions is required.
  - Intended Use description: The tool's role should be defined precisely; note if it is purely assisting with documentation or recommending CAPAs that could impact trial integrity, data reliability, and patient safety within the trial.
  - **Risk management:** Analyze risk (incorrect deviation classification, inappropriate CAPA suggestion, etc.) and plan for monitoring appropriateness over time.
  - **Clinical trial data integrity:** If the AI tool influences data collection, interpretation, or CAPAs, its validation must demonstrate it does not compromise data integrity.
  - Given the **continuous learning** aspect of this tool, precisely define which future modifications will be covered by PCCP.
- **UK:** High-risk classification triggers robust validation, and AI outputs must be auditable, explainable, and compliant with clinical standards.
  - **Risk classification:** Given the high-impact nature, this would be considered as a high-risk AI under UK frameworks, necessitating stricter controls, monitoring, and validation procedures.
    - **Highly regulated:** Clinical trials are highly regulated (e.g., MHRA). Any AI used must align to clinical and ethical standards.
  - **Robust governance:** AI use in clinical trials must be documented and auditable and is subject to strict governance protocols.
  - **Data integrity and validation:** Generated content must be accurate, traceable, and reliable. The output must be validated.
  - **Governance:** The organization must assign responsibility for AI decisions and ensure oversight mechanisms are in place.
- **China:** Subject to registration and privacy compliance; and clinical data is likely considered regulatory.
  - As it relates to clinical trial data, there is a greater likelihood that such data will be defined by the Chinese government as regulatory data requiring compliance with relevant laws and regulations.
  - Because personal information is involved, regulatory constraints on the cross-border movement of data need to be considered.
  - Registration with authorities is needed if an application is public-facing, and confirmation of authorities is needed to proceed.
- **India:** ICMR guidelines and DPDPA govern ethical and data practices; the absence of a clear CDSCO pathway creates approval ambiguity.
  - India currently lacks a dedicated AI regulatory framework, but some of the considerations from the Data Privacy Act and guidelines issued by ICMR and NITI Aayog would be applicable:
    - **ICMR ethical alignment:** The AI tool's function must align with ICMR ethical guidelines for trial oversight (reporting, safety), subject to EC review. (ICMR Guidelines)
    - **Regulatory framework and compliance:** Adhere to existing laws such as the Information Technology Act 2000 and the DPDPA 2023, while following sector-specific guidelines from regulatory bodies like the Reserve Bank of India (RBI) and Security and Exchange Board of India (SEBI). Government initiatives such as NITI Aayog's Responsible AI for All strategy and the AI Task Force by MeitY aim to create ethical and legally compliant AI ecosystems.
    - **ICMR** has also released **Ethical guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare**. While these guidelines focus on ethical considerations in research and health care AI, they highlight important principles like data privacy, transparency, accountability, and safety, which are relevant to complaint management and protocol deviations.

- **Japan:** Subject to GCP and APPI rules, and documentation, traceability, and human supervision are mandatory. Japan does not have specific regulation dedicated to the use of AI in protocol deviation management. Such use is covered under existing regulation frameworks including GCP, APPI, etc.
  - **Regulatory scope:** Assess whether the AI technology influences diagnosis, treatment, or patient care decisions. If the AI is used purely for clinical trial oversight (e.g., managing protocol deviations), it is generally not considered a medical device and therefore does not require PMD Act approval. However, if AI influences clinical decision-making during a trial (including indirect influence), such as recommending medical interventions based on patterns of deviation or indirectly triggering changes in treatment regimens, then it could be defined as a medical device under the PMD Act.
  - **Human supervision is mandatory:** AI cannot autonomously classify or handle protocol deviations. Humans must review and confirm.
  - **Recordkeeping:** The Ministry of Health, Labour and Welfare's (MHLW) GCP Ordinance requires all clinical trial activities—including protocol deviation detection—to be fully documented, traceable, and auditable.[114]
  - **Audit readiness and rigorous documentation:** All information related to protocol deviation management must be thoroughly documented, including which data the AI analyzed, which deviations were flagged, and who reviewed the AI-flagged deviations. All AI actions must be logged and retrievable during inspections by Pharmaceuticals and Medical Devices Agency (PMDA) or MHLW.
  - **Validation:** The AI/ML system used for protocol deviation management must be validated for accuracy and reliability to ensure that it functions as intended.
  - **Explainable:** PMDA inspectors may ask how protocol deviations were identified; therefore, the logic of the AI must be explainable.
  - **Data privacy:** When AI/ML models are trained using historical or real-world subject data, the training data set may contain potentially identifiable information such as patient ID, age, medical history, lab results, etc. In such cases, companies are required to ensure compliance with the APPI, including de-identifying personal information, obtaining consent from trial participants for the use of their data in AI training, maintaining detailed records on what data was used, etc.
- **Global regulatory standard-setting organizations:** ISO, NIST, GAMP, and WHO provide guidance on risk classification, AI validation, transparency, and documentation.
  - **Classification:** Assess the use case based on the design principles of autonomy and control. (GAMP) The use case may be classified as a high-risk AI system due to its direct impact on product quality. (GAMP)
  - **Implement controls** to govern, map, measure, and monitor the AI development lifecycle. (NIST)
  - **Third-party entities:** The technologies acquired from third-party entities may be complex or opaque, and risk tolerances may not align with the deploying or operating organization. (NIST)
  - **Human in the loop:** If there is no human in the loop, it may be a restricted system (US + EU AI Act). Human-in-the-loop references the need for an additional review by a human that AI is performing as intended.
  - **Preapproval registration vs. HA preapproval:** Article 49: Registration | EU Artificial Intelligence Act
  - **Intellectual property:** Eased production or replication of alleged copyrighted, trademarked, or licensed content without authorization; also eased exposure of trade secrets; or plagiarism or illegal replication related to third-party entities. (NIST)
  - **Confabulation/hallucination:** The production of confidently stated but erroneous or false content—identify and correct for GenAI. (NIST)
  - **Documentation:** Comprehensive documentation, including audit logs and transparency, will be necessary. (7.5 of ISO 42001)

Key takeaways

- While common AI principles such as bias prevention, transparency, and data privacy are broadly supported, countries differ in their classification schemes, validation standards, human oversight rules, and change control/update management.
- Life sciences companies should align each use case with a jurisdiction's risk appetite, privacy protections, and regulatory maturity.
- The proper AI deployment strategy depends on the application's nature and features, market priorities, and companies' tolerance for regulatory complexity.

By proactively managing AI governance and anticipating divergent requirements, companies can be future-ready with their AI strategy across markets and avoid costly compliance pitfalls.

What to do now: Strategic steps for AI readiness

As the regulatory landscape evolves, life sciences companies can't afford to wait for clarity. Proactive action is a leading path forward. Here are some considerations for moving from reactive compliance to strategic readiness:

Conduct a strategic AI readiness assessment: Instead of assuming a full suite of AI systems already exists, start by identifying the most high-impact opportunities for future AI deployment. Prioritize use cases with clear value, then assess the quality of your underlying data systems. Begin cleaning, structuring, and tagging data sets to support future model development. In parallel, map out the regulatory environments across all jurisdictions where you operate and establish a monitoring process to track emerging policies. A proactive, well-governed foundation today can accelerate scalable AI adoption tomorrow.

Classify AI risk with precision: Leverage frameworks like the EU AI Act or an industry-specific AI risk and control framework[115] to categorize AI systems by risk level. High-risk systems—particularly those affecting patient safety or clinical outcomes—require stringent documentation, validation, and oversight. Implement AI risk registers to continuously monitor evolving risk profiles as the regulatory AI landscape changes.

Establish cross-functional governance and innovation processes: Form an AI oversight committee that includes stakeholders from legal, clinical, data science, IT, and regulatory affairs. This isn't just about compliance; it's about embedding AI governance into the company's strategic foundation. In parallel, develop a standardized AI innovation process to ensure every model—regardless of use case—follows a consistent approach to data quality, validation, transparency, and risk mitigation regardless of the jurisdictions targeted. A unified framework helps maintain oversight, accelerates approvals, and can confirm global AI development aligns with both regulatory requirements and enterprise goals.

Build AI transparency from the ground up: Develop AI "nutrition labels" that clearly outline data sources, algorithmic logic, decision-making pathways, and bias mitigation efforts. This transparency not only can facilitate regulatory reviews but also can reinforce stakeholder trust in AI systems.

Engage regulators early and leverage available tools: Don't wait until submission to initiate conversations. Begin engaging with regulatory authorities early to align expectations, surface potential red flags, and clarify approval pathways. In jurisdictions like the EU and China, this can help mitigate the risk of delays, audits, or post-market interventions. Where available, take advantage of regulatory tools such as the UK's AI Airlock sandbox[116] or similar innovation programs to test AI systems in controlled environments and gain regulatory insight before launch.

These aren't just compliance moves. They're strategic imperatives that position your AI systems as market-ready, risk-resilient, and fully aligned with the future of global AI regulation. For life sciences companies, the window to act is now—while considering frameworks that can be scaled if enforcement intensifies.

The last word: Embracing the new AI reality

For life sciences, the regulatory landscape is no longer a distant horizon; it's the ground beneath every AI initiative. In a sector where innovation moves fast and scrutiny runs deep, compliance is no longer the last hurdle before market entry. It's the proving ground where credibility is won or lost. The AI tools reshaping drug discovery, medical device development, clinical trials, and patient care now need to pass a new litmus test: Can they be trusted? Can they be explained? Can they be defended? And are they compliant?

The answers lie not in waiting for regulatory clarity but in leading it. The companies that position regulation as a strategic function—not a reactive task—will likely be the ones that rise to the top. AI systems that are transparent, explainable, and risk calibrated won't just meet regulatory standards; they'll redefine them. They'll set the bar higher, making AI a force for trust, not just transformation.

In the race to lead AI-driven health innovation, the winners won't be those who simply comply, but those who wield responsibility as a strategic advantage. In the era of regulated intelligence, playing by the rules isn't a burden. It's the new power move.

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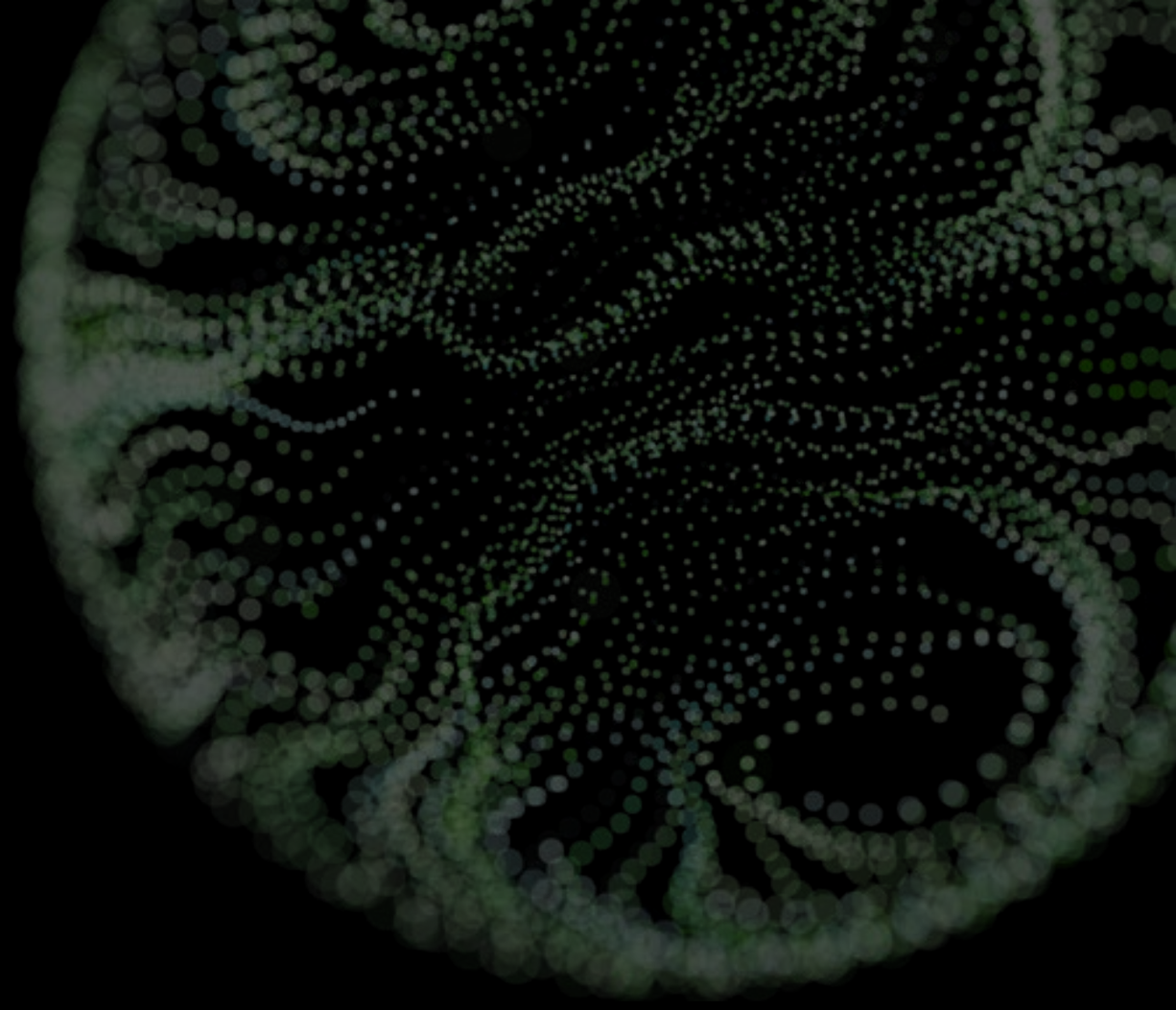

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