CLIAS

CENTRO DE INTELIGENCIA
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PARA AMÉRICA LATINA
Y EL CARIBE

Regulation of Artificial Intelligence in the Health Sector:
A GLOBAL AND REGIONAL ANALYSIS IN LATIN AMERICA AND THE CARIBBEAN

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CONTENT

KEY MESSAGES

o   Advances in artificial intelligence (AI) regulation vary significantly between different regions, however, advances in first-world countries are more developed.

o   Some countries have implemented laws through formal parliamentary processes (hard law), while others opted for more informal and flexible approaches (soft law).

o   International organizations such as the World Health Organization (WHO), Pan American Health Organization (PAHO), Organization for Economic Cooperation and Development (OECD), and United Nations Educational, Scientific, and Cultural Organization (UNESCO) have established principles and guidelines that emphasize fairness, transparency, data protection, and human oversight. These principles seek to ensure that AI is used ethically and responsibly around the world.

o   The Santiago Declaration highlights Latin America and the Caribbean (LAC)'s commitment to address AI challenges ethically and responsibly, promoting the creation of an Intergovernmental Council on AI to strengthen regional governance.

o   AI regulation needs to be flexible to adapt to rapid technological advances. Timely updates and ongoing revisions will be critical to ensure innovation and safety in the use of AI.

o   White papers and soft law, although not binding, are one more option in the search to find a regulatory path for AI.

o   Several LAC countries are generating bills inspired by the proposed European Union AI Act.

o   AI regulation must continuously evolve to stay relevant and effective. This means recognizing the unpredictability of technology and being prepared to adapt regulatory provisions as AI advances.

o   Fostering regional and international collaboration is crucial. Establishing alliances with global organizations, participating in international forums and collaboration between countries could be the way to provide access to knowledge, resources and best practices necessary to develop their own regulations in harmony with the rest of the world.

o Developing mechanisms for continuous monitoring and evaluation of AI systems is vital. Creating AI-specific agencies dedicated to overseeing the development and implementation of this technology will help maintain public trust and ensure its responsible use.

o Actively seeking AI certification standards and protocols within a flexible regulatory framework (especially on health issues), both regionally and globally, is essential to achieve reliable and secure AI systems that adapt to all regions.

o A systemic approach to regulation must integrate policymakers, scientists, and government agencies into a collaborative process that transcends sectoral and geographic barriers.

WORK TEAM

PAULA EUGENIA KOHAN: Lawyer. Diploma in Law and Innovative Technologies from Universidad Austral, with a Postgraduate Degree in Law and Artificial Intelligence from the Universidad de Buenos Aires. Master's degree in Civil Law from the Universidad Nacional de La Pampa. Diploma in Computer Procedural Law, Diploma in Digital Health Universidad de Buenos Aires. Diploma in Public Policies and Smart Governments Universidad Tecnológica Nacional, Regional Faculty Buenos Aires. Consultant Pan American Health Organization (PAHO). Senior Consultant in law and digital health at the Center for Artificial Intelligence in Health for Latin America and the Caribbean (CLIAS).

CINTIA CEJAS: Bachelor's degree in Political Science (Universidad Católica Argentina) and Master's degree in Social and Health Sciences (FLACSO-CEDES). Specialist in health project management. Coordinator of the Center for Implementation and Innovation in Health Policies (CIIPS-IECS) and the Center for Artificial Intelligence in Health for Latin America and the Caribbean (CLIAS).

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PRESENTATION

This document, prepared by the Center for Implementation and Innovation in Health Policies (CIIPS) of the Institute of Clinical and Health Effectiveness (IECS), is part of a Series of Technical Documents on Artificial Intelligence and Health (https://clias.iecs.org.ar/publicaciones/).

These documents aim to contribute to the knowledge of the region, addressing different axes and relevant perspectives in the analysis of this issue.

Aimed at health teams, health program and policy makers and decision-makers at all levels, and the general public, with a special interest in the digital transformation of the health sector and its link to sexual, reproductive and maternal health (SRH), this series of documents on AI are complemented by the activities carried out by the CLIAS (Center for Artificial Intelligence in Health for Latin America and the Caribbean) that is developed in CIIPS, with the support of the International Development Research Centre (IDRC). For more information on CLIAS, visit http://clias.iecs.org.ar

This paper discusses the regulation of artificial intelligence (AI) in the healthcare sector, highlighting the significant variations in policies and laws between different countries and regions. The approaches of international and regional organizations, as well as countries such as Japan, the United Kingdom, the European Union, Canada, among others, are examined, highlighting regulatory practices, the ethical principles involved, and the implementation of soft or non-binding regulations such as "white papers". The paper addresses how these frameworks influence the formation of AI-related policies and practices.

The analysis focuses on how AI regulation, both in general and specifically in health, must be flexible to adapt to rapid technological advancements and the need for timely updates and continuous reviews. The principles of fairness, transparency, data protection, and human oversight proposed by various organizations such as the World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD) are discussed, highlighting their importance to ensure that AI is used ethically and responsibly. Additionally, the importance of regional and international collaboration in creating regulations that allow for the sharing of knowledge, resources, and best practices is emphasized.

Lastly, the document suggests future directions for AI regulation in Latin America and the Caribbean (LAC), identifying the challenges and opportunities in the region. It proposes the creation of an Intergovernmental AI Council to strengthen regional governance and emphasizes the need to develop regulatory frameworks that foster technological innovation and protect the fundamental rights of citizens.

01. INTRODUCTION

Artificial intelligence[1] (AI) has revolutionized many sectors, and the health sector is one of those with the greatest potential to benefit from this technology. From assisted diagnostics to personalized treatments, AI promises to transform healthcare. However, its accelerated adoption requires a regulatory framework that ensures its ethical and safe use.

Currently, regulatory developments vary significantly between countries. While some already have enacted laws, others are just beginning this process. This document examines current regulations, draft bills, and soft law instruments[1].

To begin with, it is important to understand what we mean when we mention "hard law" and "soft law", terms that are used in the regulatory field, and that we will use frequently in this document.

HARD LAW [2]	SOFT LAW
It refers to legally binding regulations, such as laws, that impose obligations and sanctions.	comprises non-binding instruments, such as white papers and ethical guidelines, that influence policies and practices without having binding legal force.

The idea of the paper is to provide an overview of the regulatory landscape for AI in the region, allowing for a detailed examination of various proposed regulatory frameworks.

In this regard, and to have an initial understanding of the concepts that make up AI governance functions, in December 2023, the UN developed the "Interim Report: Governing AI for Humanity" [3, p. 17], which details and classifies regulations according to their institutional "hardness," that is, the level of rigidity and enforceability, in a pyramidal format, from most rigid at the top to least rigid at the base. Thus, the pyramid shows how AI governance functions can vary from more general and cooperative activities to strict rules and enforcement mechanisms.

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[1] There is no global consensus on a single definition of AI, for this document we will use the OECD definition "An AI system is a machine that can, according to a set of human-defined objectives, make predictions, recommendations or make decisions that have an influence on real or virtual environments. AI systems are designed to operate with different levels of autonomy," https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449#mainText

7. Norm elaboration, compliance and accountability: development of mandatory standards, as well as the establishment of compliance and accountability mechanisms.

6. Reporting and peer reviews: creation of systems to report and review the use of AI, guaranteeing transparency and accountability.

5. International collaboration on data, compute and talent: promotion of global cooperation to share data, computational resources and talent, to achieve the Sustainable Development Goals (SDGs).

4. Facilitation of development, use-liability regimes and cross-border model training and testing: facilitate the development and use of AI, establishing liability regimes and promoting international training and testing.

3. Mediating standards, safety and risk management frameworks: creation and maintenance of standards to ensure security and risk management associated with AI.

2. Interoperability and alignment with norms: ensure that different AI systems and rules are compatible and aligned internationally.

1. Horizon scanning, building scientific consensus: Observe future trends and build basic scientific agreements on AI.

AI GOVERNANCE FUNCTIONS

INSTITUTIONAL "HARDNESS"

7. Norm elaboration, compliance and accountability

6. Reporting and peer reviews

5. International collaboration on data, compute and talent

4. Facilitation of development, use-liability regimes and cross-border model training and testing

3. Mediating standards, safety and risk management frameworks

2. Interoperability (horizontal) and alignment (vertically) with norms

1. Horizon scanning, building scientific consensus

Source: Interim Report: Governing AI for Humanity", ONU,2023.

These concepts will allow a better understanding of the scenario where measures can be articulated to regulate AI and foster innovation and development.

02. WHAT ARE THE KEY PLAYERS REGULATING?

AI, a product of human intelligence, is capable of reflecting both our most outstanding qualities and our deepest flaws. Decision-making mechanisms or models, based on automated data processing, may initially appear as objective, rational, neutral entities free of the biases inherent in human thinking. The reality, however, is that both data and the algorithmic models responsible for their automated processing can be contaminated by the same biases of those who develop them. This can occur either due to a lack of recognition or consideration of systemic biases, structural discrimination, or errors made during the design or implementation of such models. This situation poses significant challenges to transparency and accountability in the field of algorithms, difficulties in analyzing them or subjecting them to public scrutiny, as well as in ensuring that they are not unfair and inequitable in decision-making.

For this reason, **public policies, laws and regulations can support the development, implementation and use of AI systems in a way that promotes their ethical, safe and responsible use.**

2.1 WHAT DO INTERNATIONAL ORGANIZATIONS RECOMMEND?

In this vein, various international organizations, such as the World Health Organization (WHO) or the Pan American Health Organization (PAHO) as well as some countries in Asia, North America, and Europe have developed regulatory examples and ethical considerations and principles that can constitute a fundamental basis or background for the creation of new regulations (or improvement of existing ones) of AI in the region.

For the **Pan American Health Organization (PAHO),** the application of AI in the field of public health must be governed by certain criteria that mitigate the potential ethical risks associated with this technology. For this reason, it has developed 8 principles that outline a framework to guide the ethical and responsible use of AI in improving public health, ensuring that the technology serves collective well-being while respecting human rights and dignity [4]:

1. HUMAN-CENTRED APPROACH	It includes non-binding instruments, such as white papers and ethical guidelines, which influence policies and practices without having legally binding force.
2. BASED ON ETHICAL PRINCIPLES	The discussions, development and implementation of AI should be based on globally recognized ethical principles such as human dignity, beneficence, non-maleficence, autonomy and equity.
3. TRANSPARENCY	The creation of AI algorithms should be carried out through open and clear processes, with methods communicated transparently.
4. DATA SAFEGUARDING	Privacy, confidentiality and safety in data handling are essential in the development of any AI system.
5. SCIENTIFIC INTEGRITY	AI applications in public health should adhere to best scientific practices, be reliable, reproducible, fair, honest, and should allow for adequate public scrutiny.
6. ACCESSIBILITY AND COLLABORATION	Developments should be as open and shared as possible, promoting openness as an essential element for the success of any AI project.
7. EQUITY AND INCLUSION	The design and impact of AI initiatives in public health must always be based on equity, equality and inclusion, avoiding any form of discrimination.
8. HUMAN SUPERVISION	There must be human supervision and review of decisions made in an automated manner, ensuring that technology remains under the control of people.

The **World Health Organization (WHO)** has led a document focused on the ethics and governance of AI in health called "Ethics and governance of AI for health"[5], which outlines 6 key ethical principles aimed at guiding the responsible integration of AI into health. What these principles seek is **protect human autonomy, promote human well-being and safety, ensure transparency and comprehensibility of algorithms, foster accountability, ensure inclusiveness and equity**. The WHO's ethical and governance framework was designed to be integrated into all stages of the design, development and implementation of AI in health, paving the way towards harmonizing the technology with human rights and global public health needs.

The ethical principles proposed by the WHO and PAHO for the use of AI in health emphasize the **importance of maintaining human autonomy and ensuring that AI-centric**

solutions respect individual rights, prioritizing people over technical processes. This shared emphasis on autonomy is complemented by a strong commitment to **transparency, demanding clarity in the development and application of AI algorithms, privacy protection, and data safety**.

In terms of equity and inclusion, both WHO and PAHO stress the need for AI to be fair and accessible to all, underlining the importance of **avoiding any form of discrimination and coding biases. This not** only seeks to expand the access and usefulness of AI in health, but also to ensure that the principles of equality and social justice are respected.

However, there are also differences in how each organism articulates and expands upon certain principles. PAHO, for example, specifies that the development and implementation of AI must be based on explicit ethical principles such as human dignity and beneficence, providing more direct guidance on the ethical foundations that should be observed. Additionally, it emphasizes scientific integrity, underscoring the need for AI applications in public health to be reliable and subject to public scrutiny, an aspect not explicitly detailed in the WHO principles.

However, both frameworks share the common goal of **promoting an ethical and responsible use of AI in improving public health, ensuring that technology serves collective well-being and respects human rights and dignity**.

The Principles of **Organization for Economic Co-operation and Development (OECD)** Oct. 2019 on AI [6] also act as a framework to ensure that these systems are robust, secure, impartial, reliable and aligned with democratic values and human rights. These principles emphasize that **AI must serve human well-being and sustainable development, respect the rule of law and diversity, and ensure transparency and responsible disclosure**. In the field of public policies, the document recommends that governments encourage investment in innovation and development, develop accessible ecosystems for AI, establish appropriate regulatory frameworks, train the workforce, and promote international cooperation. These principles, while non-binding, have proven influential in shaping global regulations, reflecting a commitment to AI that prioritizes safety, privacy, and inclusive social benefit. Importantly, they have been considered in the drafting of Europe's AI law [7].

In this regard, in 2021 the **United Nations Educational, Scientific and Cultural Organization (UNESCO)**) developed its guidelines on the Ethics of Artificial Intelligence [8]. This document establishes a global regulatory framework to ensure the development and ethical use of AI, addressing its positive and negative impacts on society, the environment and human rights. It is based on fundamental principles that emphasize human dignity, gender equality, social justice, and sustainability, and It seeks to provide an ethical compass that guides technological advancement toward the common good, mitigating risks and fostering trust in these emerging technologies. The recommendation highlights the **need for transparency, accountability, and multi-stakeholder participation in AI governance**. It also focuses on the protection of human rights and biodiversity, as well as the promotion of

inclusive education and capacity building in AI; and underscores the importance of international collaboration to bridge digital divides and ensure that the benefits of AI are shared equitably.

For its part, the **United Nations General Assembly** [9] unanimously approved in March 2024 a Resolution whose objective is to promote the development and use of AI systems so that they are not only safe and reliable, but also contribute positively to sustainable development at a global level. This Resolution was initially promoted by the United States and endorsed by more than 120 countries, underscoring the importance of adhering to human rights principles at all stages of the design, development, implementation, and use of AI. This act marks the **This is the first time that the General Assembly has committed to establishing a regulatory framework for this emerging technology, to ensure that human rights are respected in both the digital and physical worlds, urging to avoid the use of AI systems that contravene international human rights standards.** The UN advocates for universal ethical principles to guide the global use of AI, emphasizing fairness, transparency, and accountability, and proposes to use AI against climate change and foster international collaboration, sharing advances and best practices in the use of AI, emulating the model based on the way the European Organization for Nuclear Research (CERN) [10] operates in the field of particle physics. The UN also promotes open access to AI data and models, allowing their analysis and criticism by the global community, thus ensuring ethical and safe development of the technology.

Lastly, among the collective regional and international initiatives developed by organizations and countries, it is worth noting that, in 2023, during a meeting in Japan, leaders of the **G7** (Canada, France, Germany, Italy, Japan and the United Kingdom) initiated the "Hiroshima Process" [11] to address the challenges of generative AI. This declaration highlighted the innovative opportunities and transformative potential of advanced artificial intelligence systems, particularly grassroots models and generative AI. The G7 leaders acknowledged the need to manage risks and protect people, society, and shared principles, including the rule of law and democratic values, keeping humanity at the centre. The Declaration also highlights the creation of an inclusive governance framework for AI and instructs to accelerate the development of the AI Hiroshima Process Comprehensive Policy Framework in collaboration with the Global Partnership for Artificial Intelligence (GPAI) and the Organization for Economic Cooperation and Development (OECD). In this way, they anticipate that these joint efforts will foster an open and enabling environment where safe, trustworthy, and trustworthy AI systems are designed, developed, deployed, and used to maximize the benefits of the technology and mitigate its risks, for the benefit of the global common good. Importantly, although the decisions taken by the G7 are not legally binding, **Their political influence is crucial in the global landscape**.

2.2 WHAT IS THE LEGISLATIVE STATUS OF AI GLOBALLY?

The examples mentioned above illustrate the considerable interest that has been aroused by the need to generate regulatory frameworks for AI and other emerging technologies at the international and regional levels. Globally, **the discussion of AI in legislative procedures has experienced a notable increase.**

According to Stanford University's Artificial Intelligence Index Report 2024 [12] the **mentions of AI in legislative areas nearly doubled, from 1,247 in 2022 to 2,175 in 2023**. Over the past year, lawmakers from 49 countries have addressed AI in their deliberations, highlighting the truly global reach of the political discourse on this technology. Moreover, in 2023, at least one country on every continent discussed AI, underscoring the universality of its impact and relevance.

According to the report's analysis, legislation mentioning "artificial intelligence" was examined in 128 countries during this period. Of these countries, 32 have enacted at least one AI-related law. In total, 148 AI-related laws have been passed worldwide. Although 2023 saw a decrease in the total number of laws passed compared to the previous year (28 vs. 39), **the number of AI-related laws passed in 2023 is significantly higher than in 2016. This wave of regulatory activity reflects a recognition of the urgency of governing AI. However, analyzing what type of regulation will be appropriate is crucial because AI is characterized by a hyper-accelerated capacity for evolution that defies what is known today in regulatory matters**.

JAPAN

The Artificial Intelligence White Paper by **Japan** [13], seeks to take a flexible approach to AI regulation, without imposing restrictions that could slow down technological advancement. To this end, it proposes to focus on comparative analysis with regulations in other regions, such as the European Union and the United States, and on the study of areas that require specific measures, including the protection of human rights and national security. The fact that Japan has selected the "white paper" as a regulatory format indicates that they are looking for an approach that includes active participation in the creation of international standards and agile regulation that adapts to rapid technological changes. It also suggests the combination of guidelines and standards to allow timely updates and continuous review of existing regulations, fostering an environment for innovation. The document does not directly specify regulations or policies on intellectual property related to generative AI[2], however, mentions the importance of discussing the interpretation of intellectual property laws in relation to generative AI, suggesting the possibility of establishing guidelines to promote technological progress while preventing its misuse.

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[2] The issue of intellectual property in reference to generative AI is a topic of legal discussion that has not yet been resolved worldwide.

In summary, Japan is working to address these risks by promoting a flexible governance-based approach through its soft law and modification of specific existing regulations such as reforms to intellectual property law, seeking to develop a regulatory system that allows innovation and the safe use of AI.

UNITED KINGDOM

The UK's National AI Strategy [14], in use since 2023, is characterized by its adaptability and focus on innovation, and it was designed to respond agilely to rapid technological evolutions. This strategy also focuses on strengthening regulatory capacity through effective coordination between government agencies, which includes the creation of a central hub that monitors and assesses AI risks across the economy, thereby supporting regulatory coherence.

An example is the initiative of the National Health Service (NHS) with its Artificial Intelligence Deployment Platform Pilot (AIDP)[3] [15] which seeks to integrate and centralize the deployment of AI tools in health systems nationwide, providing access to a curated catalog of AI models, which operates by connecting multiple hospital sites to a cloud-based system, enabling the centralized deployment of AI technologies, such as radiology tools. This approach not only improves the efficiency of workflows and clinical outcomes, but also establishes a uniform framework for information governance and AI model management, ensuring that all devices and procedures are aligned with national standards.

EUROPEAN UNION

On March 13, 2024, the **European Parliament** passed legislation [16] of **binding nature on AI**, imposing stringent standards for high-risk systems before they enter the European Union (EU) market. The law, known as the **AI Act**, was created to prioritise the safety of AI products and services in the EU market. To that end, they implemented specific principles and requirements that are commonly used in the field of product safety, such as continuous market monitoring to identify and correct safety issues related to AI products, procedures to verify that AI products comply with established safety standards and regulations before they are commercialized, among other aspects.

The European AI Act was published on July 12, 2024, in the Official Journal of the European Union. It comes into force on August 1, 2024, and will be fully applicable 24 months thereafter, except for certain exceptions[4]. It is intended to apply to providers and users of AI systems within the EU, as well as to external providers and users, provided that the results

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[3] A process followed by the National Health Service (NHS) in England/DHSC to use personal data in AI diagnostics and their assessment and ethnicity, and is used to present in user dashboards and model validation reports.

[4] Exceptions: prohibitions on prohibited practices (6 months thereafter), codes of practice (9 months thereafter), standards for general-purpose AI, including governance (12 months thereafter), and obligations for high-risk systems (36 months thereafter).

of the AI system are used in the EU. This includes AI systems that affect EU citizens, regardless of where the provider or user of the AI system is located. The objective is to ensure that all AI systems operating within the EU follow a consistent set of ethical and safety standards. In this regard, the EU AI Act is structured around four risk categories for AI systems: prohibited, high risk, limited risk, and minimal risk. Each category prescribes various measures, detailed in the law, based on the risk that relevant actors in the AI lifecycle must take and implement.

To strengthen compliance with and oversight of these standards, the European AI Office has been established within the European Commission. This Office not only oversees the implementation of the law, but also actively participates in international dialogue and cooperation on AI issues, seeking to position Europe as a leader in the ethical and sustainable development of these technologies.

According to Article 6(1), if the AI system is used as a safety component of a medical product (e.g. medical devices or diagnostic tools) regulated under the European Union harmonization legislation listed in Annex I, it will be considered high-risk.

This is especially relevant since AI systems in the healthcare sector obviously have a direct impact on the health and safety of patients, and any error or failure in these systems can result in serious consequences, including physical harm and risk to life. It is important to note that European **law does not regulate liability for damages resulting from AI.** However, what it does indicate is that in the event of damage, Directive 85/374/EEC, which regulates liability for defective products, will apply, which details that in the event of damage, the plaintiff must prove that he or she has suffered it as a direct result of the use of the AI system in question.

CANADA

The **Artificial Intelligence and Data Act (AIDA)** [17] presented by the Government of **Canada** in June 2022, as part of the Digital Charter Implementation Act of 2022 (Bill C-27) [18], marks an important milestone in trying to ensure that Canadians can trust the digital technologies they use every day. AIDA proposes a regulatory framework that positively guides AI innovation and encourages the responsible adoption of AI technologies by Canadians and businesses in the country. The approach is based on transparency and seeks to align with international standards, collaborating with global partners such as the European Union, the United Kingdom, and the United States. The rapid expansion and capabilities of AI have also raised concerns about potential harmful or discriminatory outcomes, so AIDA sought to address these concerns by setting clear standards for managing the technology responsibly. The proposal includes a risk-based framework for high-impact AI systems[5] which will be developed in consultation with other stakeholders to

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[5] The Government considers that the following are some of the key factors that need to be examined to determine which AI systems would be considered high-impact: Evidence of risks of harm to health and safety or a risk of adverse impact on human rights, based on both the intended purpose and potential unintended consequences; the severity of the possible damage; the scale of use; the

protect the interests of the Canadian public. Canada's approach is dynamic, planning to adapt AI regulation as technology evolves, through consultations[6] and an open and transparent regulatory development process.

UNITED STATES

The United States lacks a comprehensive federal law specifically aimed at AI governance, however, an Executive Order (EO) has been issued to direct the federal government's policy and practice regarding AI governance, and some states have also proposed and enacted AI laws.

According to the "AI Index 2024 Annual Report" [12], a significant increase in AI regulation has been observed in the United States, especially since 2016, while in that year only one AI-related regulation was recorded, in 2023 this number rose to 25. **Interest in AI among U.S. lawmakers has also grown exponentially; in 2023, 181 AI-related bills were proposed at the federal level, more than double the 88 proposed in 2022.**

The **number of regulatory agencies focusing on AI has also increased, from 17 in 2022 to 21 in 2023**. This increase indicates a growing concern on the part of a broader spectrum of U.S. regulatory bodies.

The Executive Order[7] (EO) on the U.S. Government's Development and Safe and Reliable Use of Artificial Intelligence [19] issued on October 30, 2023, introduces a series of regulatory measures aimed at managing the potential risks that AI could pose to the national, economic, and public health security of that country. This EO represents a significant step in the regulation of AI in the United States, particularly as it relates to the safety and reliability of AI systems. The EO also introduces new guidelines for the conduct of comprehensive "red-teaming"[8] tests. These tests are essential for identifying and mitigating vulnerabilities

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nature of the damage or adverse impacts that have already taken place; the extent that for practical or legal reasons it is not reasonably possible to opt out of using that system; imbalances in economic or social circumstances, or the age of the people affected; and the degree to which the risks are adequately regulated under another law." https://ised-isde.canada.ca/site/innovation-better-canada/en/artificial-intelligence-and-data-act-aida-companion-document#s6

[6] The stakeholder consultation process is crucial to developing effective and adaptive AI regulations in Canada, as outlined in the Artificial Intelligence and Data Act, these consultations will gather a wide range of perspectives and ensure that legislation is balanced, fair and effective.

[7] An executive order from the President of the United States is a directive issued by the President to officials and agencies of the federal government. Executive orders have the force of law, but they do not require congressional approval. These directives allow the president to manage the operations of the federal government and ensure that laws and policies are implemented according to his interpretations and priorities. Although executive orders are powerful, they can be subject to legal challenges in court if they are deemed to exceed the president's authority or violate the Constitution. Authors' note: In continental or civil law systems, such as those found in Europe and Latin America for example, the figure that most resembles an executive order could be the decree issued by a head of state or government
https://en.wikisource.org/wiki/Executive_Orders_and_Proclamations#1

[8] "Red-teaming," the process of testing technology to find inaccuracies and biases in it, is something that typically occurs internally in tech companies. But as AI develops rapidly and becomes more widespread, the White House has encouraged major tech
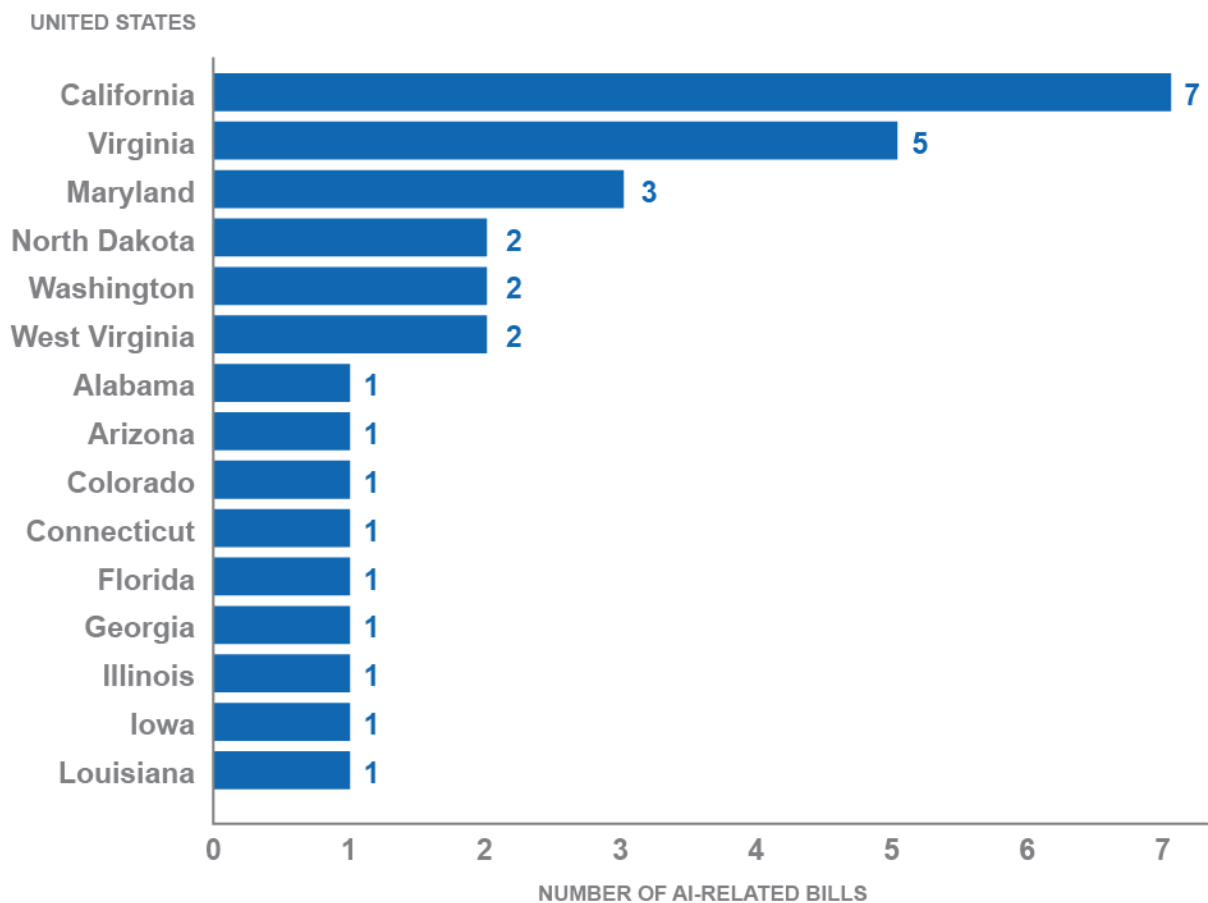
in AI models before they are deployed, highlighting the importance of rigorous assessment to ensure systems are both accurate and fair.

However, while the EO allows for some oversight over companies' new products, there is still a general lack of enforcement power.

In summary, the EO seeks to establish a robust framework for the safe and responsible development of AI technology, balancing innovation and regulation, while preparing the federal government to lead, for example, in managing advances in AI.

As previously mentioned, this did not prevent regulatory developments from existing at the state level. According to the document "The AI Index 2024 Annual Report," data on the enactment of AI-related laws at the state level (2023) can also be observed [12]:

UNITED STATES

State	Number of AI-related bills
California	7
Virginia	5
Maryland	3
North Dakota	2
Washington	2
West Virginia	2
Alabama	1
Arizona	1
Colorado	1
Connecticut	1
Florida	1
Georgia	1
Illinois	1
Iowa	1
Louisiana	1

NUMBER OF AI-RELATED BILLS

Source: IA Index, 2024.

The EO is crucial to understanding how AI is intended to be ethically, safely and efficiently integrated into the healthcare sector. The guidelines include the development of predictive

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companies like Google and OpenAI, ChatGPT's parent company, to have their models tested by independent hackers
https://www.npr.org/2023/08/26/1195662267/ai-is-biased-the-white-house-is-working-with-hackers-to-try-to-fix-that

and generative technologies to improve quality measurement, benefits management and patient experience, using AI to anticipate needs and optimize resources. The importance of continuous monitoring of the safety and performance of these technologies in real environments is emphasized to ensure their effectiveness and mitigate potential risks. In addition, it highlights the need to incorporate equity principles in the design and deployment of AI technologies, using disaggregated data to prevent discrimination and ensure an equitable distribution of the benefits of AI. It also promotes the establishment of robust security and privacy standards throughout the AI software development lifecycle, protecting patients' personal and sensitive information. In addition, it encourages collaboration with state and local health agencies to share best practices and learnings, and promote positive uses of AI in the sector to improve efficiency and job satisfaction.

For the implementation of these guidelines, the EO requires the Secretary of Health to develop detailed and practical strategies to evaluate the performance of AI-based health tools and establish assurance policies. This includes promoting compliance with federal anti-discrimination laws and establishing an AI safety program that collaborates with patient safety organizations. These measures underscore the importance of a responsible approach towards integrating AI into healthcare, maximizing benefits while minimizing risks and protecting patients' integrity and privacy.

The Executive Order also focuses on keeping the United States at the forefront of AI research, through the expansion of grants to key sectors such as health and climate change, supported by a new pilot program called the National AI Research Resource.

It should also be noted that, in line with the United States' long tradition of favoring a self-regulatory approach in the industry, informal engagements have also been a key tool in its regulatory approach to AI. For example, in July 2023, Amazon, Google, Meta, Microsoft, and other AI companies met at the White House and voluntarily committed to following principles related to safety, security, and trust in AI. These principles include ensuring that products are secure before they are released to the market and prioritizing investments in cybersecurity and security risk protection measures.

2.3 GLOBAL PERSPECTIVES, IN SUMMARY

For AI regulation to achieve its objectives, it will be essential to adapt to the distinctive characteristics of this technology. For this reason**, those involved in AI governance and regulation must recognize the unpredictability of this technology and consider the possibility that the form and procedure of current regulatory provisions may become inadequate or even irrelevant in the not-too-distant future**.

The fundamental challenge when it comes to regulatory developments related to AI lies in how to ensure that advanced and potentially unlimited intelligence systems remain under strict human supervision [20].

The truth is that the use of AI in health presents several challenges that cannot be solved by agreeing on ethical principles alone, in particular because the risks and opportunities of the use of AI are not yet fully understood and will surely change over time, this makes the need to agree on governance around this technology even more relevant.

In conclusion, at a global level, AI regulation has taken a path focused on promoting ethical, safe, and responsible use. Entities such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO) have been pioneers in establishing principles that guide the implementation of AI in public health, ensuring that these technologies advance with respect for human dignity and equity. These principles range from transparency in the development of algorithms to inclusion and human supervision, seeking to make AI not only a technical tool, but also an instrument for collective well-being. Simultaneously, countries in various regions, including Asia, North America, and Europe, have been adopting and adapting these principles to their national regulatory contexts, evidencing a growing concern about the ethical and social impacts of AI.

All these initiatives show a clear pattern: **there is an emerging consensus on the need to regulate AI in ways that respect human rights and promote social welfare.** This consensus is guiding key players towards a future where AI is not only a tool for technological progress, but also a catalyst for sustainable development and social equity. **The key to success in this regulatory endeavour will be the ability to adapt to a rapidly evolving technology, ensuring that legal and ethical frameworks can respond effectively to the future challenges that AI may present.**

Table 1 summarizes the main regulations mentioned in this section.

COUNTRY / ORGANIZATION	TYPE OF REGULATION	MAIN FEATURES
WORLD HEALTH ORGANIZATION (WHO)	**Eticas guidelines**	Emphasis on global ethical principles Fairness and justice Data Transparency and Privacy
PAN AMERICAN HEALTH ORGANIZATION (PAHO)	**Eticas guidelines**	Specific ethical principles for public health Equity and inclusion Human oversight and review
UNITED NATIONS	**Governance guidelines**	Promotion of universal ethical principles Using AI against climate change

		Fostering international collaboration
G7 AND HIROSHIMA	**Hiroshima Process**	Focus on generative AI governance Comprehensive Policy Framework - Cooperation with GPAI and OECD
EUROPEAN UNION	**Law**	Risk categorization Transparency and explainability. Human monitoring data protection.
UNITED STATES	**Executive Order on AI (decree)**	"Red teaming" Testing Public-Private Cooperation Focus on National Security – Promoting Transparency
CANADA	**Soft law**	Risk-based framework privacy and data protection public consultations. Focus on international interoperability
JAPAN	**Soft law**	Regulatory flexibility. Fostering innovation. Protection of human rights and national security.
UNITED KINGDOM	**Soft law**	Adaptability and innovation orientation. Effective interagency coordination. Focus on safety and ethics.

03. WHAT IS THE OUTLOOK FOR AI REGULATION IN LATIN AMERICA AND THE CARIBBEAN?

El The **scenario in our region is diverse and is in different stages of development**, with some countries advancing legislative proposals and others still without concrete initiatives. Most Latin American countries propose regulations inspired by or with significant similarities to the European Union Artificial Intelligence Act (AI Act).

An important milestone in the region in the field of AI, **it is the Declaration of Santiago**[9] [21], adopted in October 2023 during the Forum on the Ethics of Artificial Intelligence in Latin America and the Caribbean. This declaration articulates a regional commitment to address both the opportunities and challenges presented by AI. It emphasizes the need for an ethical and responsible approach in the development and use of AI, highlighting the **importance of aligning these technologies with universal human rights and international standards**. The Declaration proposes the creation of an Intergovernmental Council on Artificial Intelligence for Latin America and the Caribbean, with the aim of strengthening governance and regional collaboration in this area.

The importance of the Santiago Declaration lies in its proactive approach to managing AI, promoting a broad regional dialogue that includes States, civil society, the private sector, and academia. This approach is crucial to ensure that AI is developed in a way that respects the region's specific cultural and social values and to mitigate the risks of exclusion, discrimination, and privacy violations.

The regulations that will be mentioned below focus exclusively on the specific regulation of the use of AI, such as a bill or parliamentary law already enacted, excluding public policy projects, laws that include the issue of AI but that this technology is not the central axis of the law or AI development strategies in the countries.

ARGENTINA

In Argentina, during 2023, various legislative proposals were presented in the National Congress that seek to regulate AI technologies. Although these initiatives have not yet been included in the legislative agenda for discussion, they stand out for their focus on the ethical and responsible regulation of AI, with a marked interest in protecting human rights, privacy,

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[9] The document was signed by Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Peru, Paraguay, Santa Lucía, San Vincente y las Granadinas, Suriname, Uruguay and Venezuela.

and promoting transparency. One of these proposals is File 2505-D-2023 [22], which proposes a legal framework for the development and use of AI in Argentina. This initiative aims to ensure the protection of human dignity and equity, and establishes civil liability for damages caused by AI systems, both for developers and users. In addition, it introduces a **risk classification similar to that adopted by the European Union, which involves assessing and mitigating the risks associated with AI on a proportional basis**. Significantly, it proposes the creation of an Artificial Intelligence Supervisory Authority, an independent entity tasked with managing a registry of AI systems and exercising sanctioning powers.

The project reflects a concern for technological progress in the context of an ethical and legal framework that guarantees respect for the fundamental rights and integrity of individuals, while promoting innovation and international cooperation in the field of artificial intelligence.

BRAZIL

In Brazil, Bill No. 2338 of 2023 [23] marks an important step in the regulation of AI within the country, proposing a legal framework that not only seeks to promote technological development, but also to ensure that this advance is carried out in an ethical and safe way. This project has as its main objective to establish clear regulations for the development, implementation and use of AI systems, with a strong focus on the protection of fundamental rights and the guarantee that these systems are reliable and safe to contribute to human well-being and scientific and technological advancement. In terms of governance, the project proposes a risk categorization for AI systems, establishing stricter controls and governance measures for those considered high risk. This includes the **conducting algorithmic impact assessments to identify and mitigate potential risks prior to implementation**. In the aspect of civil liability, it is established that providers and operators of AI systems will be directly liable for any damage caused by failures or malfunctions of their systems, with special attention to high-risk systems, where strict liability applies.

CHILE

In Chile, the AI Bill Message No. 063-372 of May 2024 [24] seeks to regulate the development and use of AI in an ethical and responsible manner, ensuring the protection of fundamental rights. It focuses its efforts on clearly defining the categorization of AI systems according to their level of risk, from unacceptable risks to limited risk levels, and establishes specific regulations for each category. In the field of health, this law underscores the need for AI systems that are not only effective but also safe, insisting that they must be designed with adequate human oversight mechanisms to prevent errors and biases, especially in critical medical decisions. High-risk systems, such as those used in healthcare, must comply with rigorous regulations to ensure the safety and respect of patients' fundamental rights. Regarding civil liability, the project assigns responsibility to the operators of AI systems for any harm these systems may cause, highlighting an objective liability approach for high-risk

systems. This reflects greater severity in the expectations of safety and effectiveness for technologies applied in critical contexts such as medical and healthcare.

COLOMBIA

The draft Law PLE.200-2023C in Colombia [25] seeks to establish a regulatory framework for AI, with the aim of guaranteeing its development and use within a context that respects and protects human rights. The law focuses on adjusting AI to ethical standards, ensuring that public and private entities that develop and use AI technologies handle personal data responsibly. The project proposes a series of fundamental principles such as the centrality of the human person, respect for human rights, protection of the environment, privacy, and data security. It also emphasizes the importance of transparency, fairness, and accountability in all phases of AI development and implementation. In addition, the project classifies AI systems according to their level of risk, from unacceptable to non-existent, which determines the monitoring and control measures to be applied. It establishes the need for informed consent by users for the processing of their data and the risks associated with the use of AI. To ensure compliance with these regulations, the Superintendence of Industry and Commerce is assigned the responsibility of supervising the implementation of the law. The following are contemplated **algorithm audits and a certification platform for AI systems to verify their compliance with human rights and established principles**.

COSTA RICA

Costa Rica's Bill 23.771 [26] proposes a regulatory framework to regulate the development, implementation and use of AI, aligned with the principles and rights of the Political Constitution of 1949. It aims to safeguard people's dignity, human rights, and well-being in the face of advances in AI. It introduces essential definitions in the field of AI, such as algorithmic accountability and algorithmic bias, and establishes ethical principles such as fairness, responsibility, and privacy, seeking to ensure that AI is developed in a way that is fair and respectful of human rights. The regulation proposes the creation of the Artificial Intelligence Regulatory Authority (ARIA), in charge of supervising, auditing, and sanctioning the use of AI, ensuring that the established regulations are complied with. In addition, emphasis is placed on conducting impact assessments for high-risk AI systems, in order to mitigate bias and promote transparency. **It specifically regulates the use of AI in critical sectors such as health, finance, and education, to promote safety and efficiency**. The law also provides for the protection of labor rights in the context of automation and establishes sanctions to ensure compliance with its provisions. It proposes a dynamic process for the review and updating of the regulatory framework, allowing adaptations to technological advances and social needs.

ECUADOR

In June 2024, the "Bill to regulate and promote the use of Artificial Intelligence (AI) in Ecuador" was presented[27] The project seeks to develop a comprehensive regulatory

framework to regulate the current and future impact of AI on fundamental rights. The provisions include establishing four levels of risk, ,easures related to data protection, data biases and the creation of a National AI Agency, among others.

MEXICO

The bill in Mexico, "Law for the Ethical Regulation of Artificial Intelligence and Robotics"[28], seeks to create a regulatory framework that ensures the ethical use of AI and robotics, respecting human rights and promoting equitable development. The initiative contemplates the adaptation of Mexican legislation to the challenges of these emerging technologies, especially in ethical and privacy aspects. Central to the law is the formation of the Mexican Council of Ethics for AI and Robotics (CMETIAR), a decentralized body that would oversee the ethical implementation of these technologies in Mexico. This Council would integrate representatives from various sectors, such as government, academia, civil society and industry, to ensure a broad and diverse representation of interests. In addition, the creation of a **The National Network of Statistics on the use and monitoring of AI and robotics, which would facilitate the collection and analysis of data relevant to informed policy-making**. The law also spells out obligations for public and private entities that use these technologies, including the protection of privacy and personal data, and prohibits their use for discrimination or social manipulation.

PANAMA

The bill in Panama [29] seeks to establish a regulatory framework for the ethical and safe integration of AI in society, focusing on the protection of human rights and the promotion of technological innovation. The law makes special **attention to the impacts of AI on employment, proposing measures to protect workers from possible job displacements without compromising their rights**. The importance of **prevent malicious uses of AI, such as the spread of hate speech or the creation of digital fakes that can manipulate public opinion**. To ensure compliance with ethical principles such as transparency and privacy, it is suggested to create a supervisory entity that would conduct audits and monitor non-discrimination and security in AI systems. The proposal emphasizes non-discrimination, ensuring that AI does not perpetuate existing societal biases, and sets strict regulations for the protection of personal data. In addition, it promotes AI research and development in Panama through incentives for the creation of research centers and investment in emerging technologies, along with training in the ethical and responsible use of these technologies.

PERU

The draft Regulation of Law No. 31814 in Peru [30] seeks to provide a detailed regulatory framework for the regulation of the development, implementation, and use of AI in the country, highlighting the importance of safe, ethical, and responsible use of these technologies. The regulation focuses particularly on the protection of human rights and the

promotion of sustainable economic and social development. The regulation proposes a classification of AI systems based on the level of risk they present, focusing on those considered high risk. Systems that do not include explainability mechanisms, i.e., those that do not allow us to understand how certain results or decisions are reached, are classified as high-risk. This lack of transparency is critical, especially in contexts where decisions have legal or significant consequences on individual rights. In terms of civil liability, the regulation states that providers and operators of AI systems will be liable for any damage caused by their systems, ensuring that measures are in place to repair damage and mitigate risks. The regulation also places special emphasis on health, **classifying AI systems used in medical diagnosis or treatment as high-risk**. These systems must be handled with extreme caution to avoid errors that can have direct and serious consequences for the health and safety of patients.

URUGUAY

In 2023, a draft Law on the "Regulation of systems that use artificial intelligence" was presented [31], whose objective is to establish the obligatory nature of the **Digital labelling of systems and applications that use artificial intelligence**. This tagging or warning would allow users to know when a piece of content has been modified or created using AI. The rule would apply to providers placing AI systems on the market or putting into service, regardless of their location, to AI users in national territory, and to providers and users in other countries when the information generated is used in the national territory. The bill provides an exception for AI systems authorized by law for the detection, prevention, investigation, or prosecution of criminal offenses, as long as they are not available to the public to report violations.

REGIONAL PERSPECTIVE: CHALLENGES

As noted in the previous section, there are legislative proposals that seek to establish regulatory frameworks for the ethical and safe use of AI.

Table 2 summarizes regulatory advances that have been found so far in the region:

COUNTRY	TYPE OF REGULATIONS	KEY FEATURES
ARGENTINA	Bill	Proposes a legal framework for the ethical use of AI; focuses on the protection of human rights and risk classification; suggests the creation of an Artificial Intelligence Supervisory Authority.
BRAZIL	Bill	It sets general standards for the ethical use of AI; classifies AI systems according to the level of

		risk; It includes governance measures for high-risk systems.
CHILE	**Bill**	Focus on health and high-risk AI systems; establishes civil liability for damage caused by AI systems.
COLOMBIA	**Bill**	Define boundaries and guidance for AI; classifies AI systems into risk categories; It includes algorithmic impact assessments for high-risk systems.
COSTA RICA	**Bill**	It establishes ethical principles such as equity and transparency; defines the use of AI in key sectors; proposes the creation of a regulatory authority with supervisory and sanctioning powers.
ECUADOR	**Bill**	It establishes general rules of ethical use; classifies AI systems according to risk level; includes the creation of an AI Agency
MEXICO	**Bill**	It establishes a regulatory framework for AI and robotics; creates the Mexican Council of Ethics for Artificial Intelligence and Robotics (CMETIAR); focus on ethics and protection of personal data.
PANAMA	**Bill**	It focuses on labor protection against displacement by AI; classifies AI systems by risk; proposes an entity to supervise and ensure compliance with ethical principles.
PERU	**Law and Draft Regulations**	Promotes the ethical and sustainable use of AI; classify AI systems according to risk; It establishes measures for high-risk systems such as public health and safety.
URUGUAY	**Bill**	It establishes the mandatory nature of digital labeling for AI systems and applications; includes exceptions for AI systems in the prevention and prosecution of criminal offences.

The countries without formal progress in the specific regulation of AI as of the date of writing this document are Antigua and Barbuda, Bahamas, Barbados, Belize, Bolivia, Cuba, Dominica, Dominican Republic, El Salvador, Grenada, Guatemala, Guyana, Haiti,

Honduras, Jamaica, Nicaragua, Paraguay, Saint Kitts and Nevis, Santa Lucía, San Vicente y Las Granadinas, Suriname, Trinidad and Tobago, Venezuela[10].

According to analyzed data, the region faces significant challenges that may affect its ability to effectively integrate this technology into the health sector. The lack of regulatory frameworks in our region could translate into several problems in the future.

INEQUALITY IN ACCESS TO MEDICAL INNOVATIONS: Without clear regulation, the implementation of AI technologies could be unequal, with some regions accessing advanced technologies while others lag behind. This could exacerbate disparities in the quality and efficiency of health services.

TECHNOLOGICAL DEPENDENCE: The region could become overly dependent on foreign technologies and regulatory frameworks, limiting its ability to adapt these solutions to local needs. This dependence could compromise digital sovereignty[11] and the ability of countries to make autonomous and contextually relevant decisions in public health.

COMPETITIVENESS AND ECONOMIC DEVELOPMENT: the lack of adequate regulatory infrastructure could cause LAC to lose competitiveness in the development and implementation of AI technologies. This could slow economic progress and limit opportunities for local innovation.

LEGAL AND ETHICAL UNCERTAINTY: the absence of clear regulatory frameworks can generate legal and ethical uncertainty for both developers and users of AI technologies. This can deter investment in innovation and make it difficult to adopt new and advanced technologies.

To overcome these challenges, it is crucial that our region moves towards creating regulations that encourage technological innovation while protecting the fundamental rights of citizens. It is necessary **to develop regulatory frameworks adapted to local contexts that take into account the socio-economic and cultural particularities of the region**. In addition, **regional collaboration** and **investment in local research and development (R+D) capacities** can strengthen LAC's position in the global AI landscape.

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[10] Although a draft has been submitted recently, there is no information available on the subject.

[11] Digital sovereignty is understood as the capacity of a State to protect and influence the use and management of data and information generated in its territory as a result of the use of technologies by its citizens.

04. KEYS TO OUR REGION

Our region lags behind other parts of the world in terms of regulatory developments in AI. This lag is due, in part, to the challenging socio-economic conditions facing this part of the world, including economic inequalities, limitations in technological infrastructure, and lower investment in research and development (R+D).

While first world countries may focus on regulatory innovation and the refinement of advanced ethical standards, LAC is still trying to meet more fundamental needs such as basic infrastructure and investment in R+D. Despite these difficulties, **LAC must move firmly in creating regulatory frameworks and public policies that enable the safe adoption, ethical and equitable development of AI, progressively working towards meeting more complex and sophisticated regulatory needs.**

One way to overcome socio-economic constraints is **to foster regional and international collaboration**. Establishing alliances with global organizations, participating in international forums, and collaborating with more advanced countries in AI regulation can provide LAC with access to knowledge, resources, and best practices that are essential for developing its own regulations. In addition, the creation of a **regional consortium of AI experts** can facilitate knowledge sharing and cooperation among LAC countries, thereby strengthening their regulatory capacity.

It is also important for our region to develop mechanisms for continuous monitoring and evaluation of AI systems. Creating **dedicated regulatory agencies that oversee compliance with regulations and assess the social and ethical impact of AI** will help maintain public trust and ensure that AI is used responsibly.

The **active search for AI certification standards and protocols** within a **flexible regulatory framework**, both regionally and globally, is also a recommended path to achieve AI systems that are reliable and secure.

In the healthcare arena, the uniformity of these standards is crucial due to the sensitivity and critical importance of the applications involved. **By establishing certifying and regulatory agencies that operate under a common set of standards, Latin America and the Caribbean can ensure not only compliance with local regulations, but also alignment with international practices**. This will facilitate a seamless and reliable technology exchange, essential for the adoption of AI technologies that can transform the delivery of health services. In addition, a well-defined regulatory framework adapted to the health context is essential to prevent possible legal incidents, thus protecting both technology providers and end users.

Ultimately, this strategy ensures that AI innovations effectively contribute to improving health outcomes, while maintaining patient safety and data integrity across national borders.

This **systemic approach to regulation must integrate AI policymakers, scientists, and government agencies into a collaborative process** that transcends sectoral and geographic barriers, all within the established regulatory framework. Such cooperation will allow for the development of policies that reflect both best scientific practices and ethical and social needs.

By fostering a culture of rigorous certification and standardization in the context of a clear and effective regulatory framework, LAC will not only protect the interests of its citizens, but also contribute to the establishment of a safer and more ethical global AI market. This, in turn, will boost international competitiveness, promote trust in emerging technologies, and ensure that advances in AI are used for the common benefit.

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