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CENTRO DE INTELIGENCIA ARTIFICIAL Y SALUD PARA AMÉRICA LATINA Y EL CARIBE

Regulatory ecosystem for ARTIFICIAL INTELLIGENCE IN THE HEALTHCARE SECTOR

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CONTENTS

KEY MESSAGES

- The regulation of artificial intelligence (AI) in healthcare must be adaptable and flexible enough to keep up with rapid technological advances, preventing regulations from becoming obsolete or too restrictive.

- It is crucial to develop a balanced approach that encourages technological innovation in AI, without compromising the fundamental ethical principles of transparency, fairness and privacy that guarantee the safety and rights of individuals.

- Establishing a regulatory "menu of options" provides a set of alternatives to respond effectively and flexibly to AI regulatory needs. It could include laws, standards, certifications and best practice guidelines, among others, building a flexible and adaptable system, all of them complementary.

- Effective regulation of AI in healthcare requires ongoing cooperation between developers, healthcare professionals, regulators and civil society to anticipate challenges and ensure that the technology benefits everyone.

- Ethical principles must be at the heart of AI development and implementation, ensuring that the technology operates in a way that respects human dignity and fundamental rights.

- Encouraging the use of technical standards and certifications can help ensure that AI systems in healthcare are safe, effective and operate within accepted ethical boundaries.

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PRESENTATION

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

The purpose of these documents is to contribute to the knowledge of the region, addressing different aspects and relevant perspectives on the subject. They are intended for health teams, program and health policy makers, decision makers at all levels, and the general public with an interest in the digital transformation of the health sector and its link to sexual, reproductive and maternal health (SRMH). In addition, the Series is complemented by the activities carried out by the CLIAS (Center for Artificial Intelligence in Health for Latin America and the Caribbean) that are developed at CIIPS, with the support of the International Development Research Centre (IDRC). For more information about CLIAS, please visit http://clias.iecs.org.ar

The purpose of this document is to analyze, in an exploratory approach, the different regulation alternatives that can be adopted to provide AI with a framework that allows its development towards the service of people. The alternatives that will be addressed offer an agile response to the challenge of regulating AI, enabling the incorporation of technological innovations without compromising the security and rights of individuals.

These proposals seek to broaden the horizon of readers, showing that there are several tools available to regulate AI, beyond a law. The paper will examine various alternatives, such as codes of conduct, technical standards, ethical guidelines and regulatory sandboxes, among others. Each of these options will be analyzed in terms of their strengths and limitations.

Prior to reading the current document, it is recommended to read two technical documents of the Series, for a comprehensive understanding of the regulatory aspects of AI: **DT5. Why is it important to regulate Artificial Intelligence in the health sector**, and **DT6. Regulating Artificial Intelligence in the Health Sector: A Global and Regional Analysis in Latin America and the Caribbean.**

01. INTRODUCTION

Artificial intelligence (AI) in recent years has undergone a fast and growing evolution that is likely to have a cross-cutting impact on society as a whole.

If this situation is transferred to the regulatory universe, the challenges are even bigger. The take-off of this technology, places those in charge of formulating regulations in a more than complex position: the development of a technology that is unknown to many and, moreover, constantly evolving.

AI regulations constitute one of the most challenging tasks nowadays, mainly because, due to its cross-cutting nature, this technology has the ability to impact multiple sectors simultaneously, including the healthcare sector.

The concept of "regulatory ecosystem" in the context of this document refers to a dynamic and multifaceted set of elements that interact to establish a comprehensive regulatory framework. This ecosystem is not limited only to the enactment of laws and regulations, but also includes the implementation of national IA strategies, the adoption of quality seals and the development of monitoring mechanisms, which together contribute to a coherent and effective regulatory environment. The interconnection of these elements allows for a more agile and adaptive regulatory response to rapid technological advances, ensuring the protection of citizens' rights while fostering innovation and fair competition.

In this sense, a "regulatory ecosystem" is distinguished by its ability to evolve in line with technological developments and the needs of the health sector. By incorporating a variety of regulatory and control mechanisms, this approach allows the different parts of the regulatory system to coexist and reinforce each other. The diversity and flexibility of the tools within this ecosystem are crucial to address the challenges inherent in regulating emerging technologies such as AI, ensuring that the rules remain relevant and effective in a context of continuous change.

The field of AI technology regulation is constantly evolving. The success of the AI regulatory roadmap will depend on the ability of governments and institutions to implement these regulations in an effective and coordinated manner, ensuring the protection of individual rights and fostering an environment of innovation and fair competition. Adopting a flexible and dynamic approach will likely be essential to keep pace with the rapid advancement of this technology and ensure that regulations remain relevant and effective for years to come.

02. THE “BRUSSELS EFFECT”

The term "Brussels Effect"(1) was coined by Anu Bradford, Professor of International Law at Columbia University, to describe how European Union (EU) regulations tend to become global standards. **This concept refers to the tendency of countries outside the EU to align their own laws with European regulations, either because of their extraterritorial effect or because they are considered a model to follow.** A clear example is the General Data Protection Regulation (GDPR), which came into force in 2018 and set new privacy standards. This regulation not only raised the protection of personal data in Europe, but also forced other countries and global players(2) to adapt if they wanted to maintain their access to the European market.

Although the "Brussels Effect" does not mean that all countries will adopt EU AI regulations, Europe's cultural and economic weight on the global context makes it an undisputed benchmark in regulatory matters.

In Latin America and the Caribbean (LAC), there is a tendency to adopt regulations inspired by European models. The region has already followed in Europe's footsteps in areas such as data protection, and the same seems to be true for AI regulation. Although this alignment is neither uniform nor strict, Europe remains a key reference for many countries in the region, which adapt their regulations according to their own realities and needs.

However, although the "Brussels Effect" marks a clear trend, it is not the only way forward, nor is it a mandatory option. **In designing regulatory frameworks for AI, prudence and flexibility will be essential. The rapid evolution and complexity of AI poses challenges that require constant adaptability, while respecting local contexts and the ethical and social values of each region.**

03. ESSENTIAL PILLARS OF A REGULATORY FRAMEWORK FOR IA IN HEALTH

A regulatory framework that is considered effective should be based on essential pillars that guarantee both safety and ethics in the use of AI, especially in the healthcare sector, where decisions can have a direct impact on the life and well-being of patients. This section highlights some of these pillars.

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FUNDAMENTAL ETHICAL PRINCIPLES: It will be essential that any regulatory framework for AI in the healthcare sector be based on a sound set of ethical principles that guide the development, implementation and use of these technologies. Their inclusion ensures that AI systems are not only effective, but also safe and equitable in their application. Principles such as transparency, fairness, nonmaleficence, autonomy, privacy, accountability and equity, among others, should be at the core of any regulatory framework, ensuring that technologies respect and protect the fundamental rights of patients and other stakeholders in the healthcare system. This also fosters public trust and enables the responsible adoption of technological innovations.

CLEAR AND ACCURATE DEFINITIONS: it will be extremely important to formulate clear and precise definitions, as they are essential to avoid ambiguities that could lead to misinterpretations and hinder the implementation and enforcement of AI regulatory frameworks. At the same time, it will be equally important that these definitions be flexible enough to adapt nimbly to technological advances, and that they adjust as AI evolves, ensuring a balance between protecting rights and fostering innovation.

PREVENTING DATA BIAS IN HEALTH IA SYSTEMS: It will be extremely important that any regulatory framework for health AI includes specific mechanisms to prevent data bias. The quality and representativeness of the data sets used to train AI systems play a crucial role in avoiding prejudicial or discriminatory decisions. A precautionary approach involves ensuring that data come from diverse sources, reflecting different populations, genders, races, and socioeconomic backgrounds, thus ensuring that the results produced by AI are fair and equitable. Lack of representativeness in data can lead to the reproduction and amplification of existing biases in health systems, disproportionately affecting certain groups. For this reason, it should be a regulatory imperative that the data used is not only

of high quality, but also sufficiently diverse to prevent algorithms from perpetuating inequities or making biased decisions.

HUMAN OVERSIGHT IN HEALTH AI SYSTEMS: It will be essential that regulatory frameworks include specific mechanisms for human oversight of AI-assisted healthcare decision making. This involves qualified professionals reviewing and, where necessary, adjusting automated decisions, ensuring that these are aligned with clinical standards and patient needs. Human oversight acts as a key component to ensure that AI technologies in healthcare complement clinical judgment without replacing it, enabling safe and effective integration of these tools into medical practice. This ensures that automated decisions are used appropriately, optimizing healthcare outcomes.

CLARITY IN THE ASSIGNMENT OF ROLES AND RESPONSIBILITIES IN THE USE OF IA IN HEALTH: an effective regulatory framework for AI in healthcare should clearly contemplate the assignment of roles and responsibilities among all the actors involved in the development, implementation and use of these technologies. It will be essential for the regulation to establish who is responsible at each stage of the life cycle of AI systems, from their creation to their final use, ensuring that there are no gaps that could lead to confusion or legal problems in case of incidents or failures. This approach should include a detailed analysis of the different roles and responsibilities, ensuring that each actor clearly understands their role and obligations, whether in the design of the technology, its supervision or its use in clinical contexts.

CERTIFICATION AND STANDARDS COMPLIANCE IN HEALTH IA SYSTEMS: Including certification and standards compliance in regulatory frameworks for AI in healthcare will be essential to ensure safety, efficacy and accountability in the use of these technologies. Certification ensures that AI systems have undergone rigorous evaluation processes prior to implementation, verifying that they meet essential standards, such as data protection, technical and clinical efficacy, and respect for ethical principles and human rights. This certification process will be crucial to minimize risks, as any error or failure in an AI system in healthcare can have serious consequences for patients. In addition, compliance with standards prevents the use of inappropriate or immature technologies, ensuring that only those proven to be safe and effective are used. Likewise, certification offers confidence to both healthcare professionals and patients, promoting the adoption of these technologies with guarantees that fundamental rights are respected. Periodic recertification of AI systems will be vital to ensure that they continue to meet established standards, especially as algorithms and conditions of use evolve.

CONTINUOUS MONITORING AND EVALUATION OF AI SYSTEMS IN HEALTH: Mechanisms for continuous monitoring and evaluation are key that a regulatory framework for AI in the health sector should have. These should ensure that AI systems maintain their technical, clinical and ethical quality over time. The implementation of regular audits and the evaluation of their impact, not only in technical but also in ethical terms, will

be fundamental to ensure that these systems remain safe, effective and aligned with ethical principles. This process allows potential problems or necessary adjustments to be identified before negative consequences for patients occur.

MECHANISMS FOR UPDATING HEALTH AI REGULATIONS: It will be essential that health AI regulatory frameworks include mechanisms that allow for regular and flexible updates, adapting efficiently to rapid technological progress. The speed with which AI evolves requires that regulations should not become obsolete, and that they should be kept under constant review to ensure their relevance and effectiveness. These mechanisms should be agile, enabling updating without the need for complex changes or reworking the entire legal framework. The key is to allow for timely and rapid adjustments in specific areas as technologies evolve, which can be achieved through periodic or modular reviews. In this way, regulations will be kept up to date regarding new applications or risks, without hindering innovation and safety in the use of AI in healthcare.

04. "OPTIONS MENU"

As noted above, the creation of a regulatory framework for the implementation of AI goes beyond the passage of a law, in that it can be manifested through a variety of instruments covering a broad spectrum of measures. The following lines address different instruments through which a regulatory scheme for AI could be configured that does not depend exclusively on legislative implementation. **Perhaps a combination of these strategies, adapted to local circumstances, could provide the most effective balance between fostering innovation and protecting public welfare and individual rights**.

The following table summarizes a menu of possible options, from which this regulation could begin to be structured, and then discussed in more detail in the following pages.

APPROACH	
HARD LAW [2]	**SOFT LAW**
Refers to legally binding regulations binding rules that impose obligations and sanctions.	Includes non-binding instruments that influence policies and practices without having legally binding force
REGULATORY OPTIONS	
1. Single law 2. Sector-specific regulations	1. Codes of conduct 2. Technical standards and certifications 3. Ethical guidelines 4. Self-regulatory agreements 5. Multi-actor forums 6. Alignment with international ethical frameworks 7. Regulatory sandbox

It is important to clarify that these are not mutually exclusive approaches, but can complement each other, contributing to the construction of the regulatory ecosystem.

HARD LAW OPTIONS FOR THE REGULATION OF THE IA

The term **"hard law"**(3) refers to a set of binding legal instruments, such as laws and treaties. These instruments have coercive force and are enforceable by the courts, providing a clear and binding legal framework for the actors involved. **In contexts where the risks associated with AI are high, hard law provides the structure and legal certainty needed to address these challenges effectively and consistently.**

Some of the options proposed by this approach are presented below:

01. SINGLE LAW: adopting a unified approach at the local, regional or even global level, establishing a comprehensive regulation covering all aspects of AI, could provide clarity and consistency in its regulation, making it easier for companies to comply and fostering public confidence.

- **Limitation:** The development of a single law is complex and its formulation and approval can be slow due to the need for consensus among multiple stakeholders. In addition, it may be too rigid to adapt quickly to technological advances.

- **Example:** Europe's comprehensive AI Act, "The AI Act"(4).

02. SECTOR-SPECIFIC REGULATION: consists of developing regulations that address specific aspects of AI such as health, safety and education, among others. It allows addressing in depth the unique challenges presented by each aspect of AI, tailoring solutions to each specific problem.

- **Limitation:** In addition to the risk of creating sector-specific regulations in terms of generating regulatory fragmentation with possible inconsistencies or loopholes between the different sectors that use AI, specific regulations face the same challenge as the comprehensive law in that their formulation and approval can also be slow and complex. As with a single law, these specialized regulations may be too rigid to adapt quickly to technological advances.

- **Example:** New York City Law 144/2021(5) regulates the use of automated tools by employers in personnel selection and evaluation processes. This regulation, aimed at high-risk applications of artificial intelligence, establishes specific rules for decisions related to the hiring and promotion of employees.

SOFT LAW OPTIONS FOR REGULATING THE IA

The term **"soft law"**(6,7) refers to a set of non-legally binding instruments that, while not possessing the coercive force of formal law, can play a fundamental role in shaping the behavior of the actors involved. The **soft law** approach is **particularly relevant in dynamic and rapidly evolving technological fields, such as AI, where the rigidity of traditional laws may not be adequate to address emerging challenges and opportunities**. Some of the options proposed by this approach are presented below:

01. CODES OF CONDUCT: provide a set of voluntary ethical standards and principles that organizations and professionals create and commit to follow. They can address issues such as transparency, accountability and fairness in the use of AI. By promoting these ethical principles, these instruments can raise standards of practice among AI developers and users, contributing to a more trustworthy and ethical technology ecosystem.

- **Limitation:** they are voluntary in nature, which implies that their adoption and compliance may be inconsistent, restricting their effectiveness as a regulatory tool, not to mention that they do not usually have clear enforcement mechanisms, which may reduce their real impact. An additional risk is that different entities develop codes of conduct with varying standards. This can lead to a lack of consistency and universality in ethical AI practices in the healthcare sector and could even be used by some organizations as a marketing strategy, promoting an image of responsibility without a real commitment to ethical practices.

- **Example:** the international guiding principles on AI and a voluntary code of conduct created by the G7 for AI developers known as the "Hiroshima Process on AI"(8).

02. TECHNICAL STANDARDS AND CERTIFICATIONS: Technical standards define detailed specifications and criteria that AI systems must meet to ensure their quality, safety and reliability. This ensures that they operate within known limits of efficacy and safety, and minimizes the risk of errors that could adversely affect patient care. Certifications, in turn, should be granted by recognized entities that evaluate and confirm that a product, service or system meets these standards. In this way, they can increase user and patient confidence in AI solutions by providing external assurance that these systems have been evaluated and meet established quality criteria.

- **Limitation:** Technical standards must be flexible enough to reach a wide range of health AI applications, but specific enough to be effective and relevant. This requires a careful balance to avoid creating standards that are too generic or prescriptive. One issue that will need to be taken into account when developing public policies that address innovation, is that the need to comply with technical standards and obtain

certifications can pose financial and technical barriers for startups and smaller entities, potentially limiting the diversity of innovations in the healthcare sector.

- **Example:** ISO/IEC 25059(9) and ISO/IEC 42001(10)[2] ISO standards are international standards developed by the International Organization for Standardization(11) (ISO), an independent, non-governmental entity that brings together standardization bodies from multiple countries. Although they are internationally recognized, certification to comply with these standards is carried out by accredited entities that may be national or international, depending on the country. Thus, while ISO standards have global scope and recognition, certification of compliance can be managed locally or globally depending on the regulations and context of each country.

03. ETHICAL GUIDELINES: provide guidance on how to address ethical dilemmas that arise in the development and application of AI, promoting practices that respect human rights, dignity and social values. These can be applied globally, as fundamental principles such as equity, justice and respect for privacy are generally accepted, enabling their adoption by a wide range of actors in the health sector.

- **Limitation:** the difficulty of this instrument is related to the fact that the ethical principles may be interpreted differently by different actors (depending on their context, idiosyncrasies and customs, among others), which may lead to inconsistencies in their application.

- **Example:** "Recommendation on the Ethics of Artificial Intelligence"(12) by UNESCO (United Nations Educational, Scientific and Cultural Organization) is a good example of an ethical guideline.

04. SELF-REGULATORY AGREEMENTS: different actors can reach voluntary agreements on how to regulate the use of AI within their field, establishing common standards of action and internal oversight mechanisms. This option suggests a regulatory model that privileges collaboration and sectoral commitment over the imposition of external regulations. When formulated by actors within the sector itself, these agreements can reflect a high degree of

[2] ISO/IEC 25059 focuses on product quality for IA systems. It is an extension of the ISO/IEC 25010 quality model, adapted to include specific aspects of AI systems. This ISO standard adds the functional adaptability subfeature, which measures the ability of the AI system to accurately acquire and use information in future predictions, and also highlights the importance of carefully measuring the correctness and incorrectness of machine learning methods, among other functions. This standard is to certify the quality of a specific AI system. An organization that wants to sell its system as reliable can use this standard to certify that its product meets the required quality standards. On the other hand, ISO/IEC 42001 sets out the requirements for an AI management system, and is designed to help organizations responsibly manage the development and use of AI-based products or services. This standard is to certify the responsible use and management of AI within an organization when they purchase or subscribe to the use of an AI, and want to ensure that they are properly managing its implementation and use.

specialization and a deep understanding of the specific needs and challenges related to the application of AI in health.

- **Limitation:** the voluntary nature of these agreements may result in inconsistent adherence and compliance, potentially leading to uneven practices and a lack of common standards in the sector. Although self-regulation refers to autonomy in decision-making, it would be advisable to align this option with external oversight by regulators to prevent these agreements from inadequately addressing critical issues such as data privacy protection, fairness and transparency.

- **Example:** the Declaration of the International University of La Rioja, Spain (UNIR) for an ethical use of Artificial Intelligence in Higher Education(13), is one of the few examples of this type of instrument found in the sector.

05. MULTI-ACTOR FORUMS: include multiple stakeholders -such as companies, academics, civil society representatives and governments- and can generate spaces for dialogue and consensus on responsible practices in the use of AI. These spaces can facilitate consensus building on ethical principles, safety standards and governance mechanisms for AI in health, promoting intersectoral collaboration in the creation of responsible policies and practices.

- **Limitation:** there is a risk that entities with greater resources or influence dominate the discourse, which could lead to bias decisions and recommendations in favor of particular interests over the common good.

- **Examples:** the meeting held in Argentina in 2022 of the Economic and Social Council(14) is a clear example of a multi-stakeholder forum. It was a meeting with national and international experts who discussed the country's potential in AI and the development of a strategy for national technological sovereignty. Another example that can be mentioned is the "Santiago Declaration to promote ethical AI in Latin America and the Caribbean"(15), which took place in Chile and was convened by the Development Bank of Latin America and the Caribbean (CAF), the Government of Chile and UNESCO, with the objective of "building a leadership space for AI governance in the region that will allow Latin America and the Caribbean to have a common voice on this global issue"(16).

06. ALIGNMENT WITH INTERNATIONAL ETHICAL FRAMEWORKS: The adherence of countries to international initiatives that promote the ethical and responsible use of AI, such as those proposed by international organizations, can help align national regulations with global standards. This approach is based on collaboration between nations and the adoption of globally established principles and standards, usually under the auspices of recognized international organizations. This fosters consistency and quality in the use of AI in healthcare globally, promoting greater harmonization in regulatory practices.

- **Limitation:** The difficulty of this option lies in the challenges that may arise in applying global principles and standards in specific local contexts due to cultural, economic and regulatory differences. This may require adaptations that maintain consistency with international standards without losing local relevance.

- **Examples:** the United Nations (UN) document "Interim Report: Governing AI for Humanity"(17), which calls for greater alignment between international norms and AI development and implementation. The report sets out a proposal to strengthen the international governance of AI by performing seven critical functions, such as identifying future risks and supporting international collaboration on data, computing capacity and talent to achieve the Sustainable Development Goals (SDGs).

07. REGULATORY SANDBOX (18,19): specifically designed to test technologies under an established regulatory framework. This allows authorities and companies to evaluate how innovations perform in a regulated context, ensuring that they comply with regulations before large-scale implementation.

- **Limitation:** this option requires careful balancing so as not to compromise consumer protection and ethical standards, and can be complex to administer. is a risk that only the largest or most well-resourced companies will have access or the ability to participate in regulatory sandboxes, which could limit the diversity of innovations and reinforce existing market positions.

- **Example:** Spain's AI Regulatory Sandbox, developed in collaboration with the European Commission, is a digital space that seeks to connect competent authorities with AI development companies to jointly define best practices when implementing the future European AI regulation and ensure its application. Chile also created a document on the subject as an input to the conversation on the implementation of an AI regulatory sandbox (20).

Each of these strategies offers a different approach to regulating AI. A combination of these strategies and their instruments, adapted to local and global circumstances, could provide the most effective balance between fostering innovation and protecting public welfare and individual rights.

05. COMPLEMENTARY INTERVENTIONS TO STRENGTHEN REGULATORY FRAMEWORKS

While regulatory strategies, both hard and soft law, are fundamental to establishing a regulatory framework, their implementation can be strengthened by complementary initiatives that are not necessarily part of that regulatory framework. These can facilitate the adoption of regulations, improve understanding of ethical and technical principles, and promote more effective integration of AI in the health sector. The following are some possible complementary activities to regulatory frameworks:

- **ESTABLISH RESEARCH FUNDS INTENDED TO EXPLORING THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF AI.** These funds could support projects that seek innovative solutions to the regulatory challenges of AI. It is important to note that such actions require proper coordination, as support for multiple individual initiatives could result in a fragmentation of efforts, with little synergy among research findings.

- **OFFER TAX INCENTIVES OR SUBSIDIES TO COMPANIES AND ORGANIZATIONS THAT DEVELOP ETHICAL AND RESPONSIBLE AI TECHNOLOGIES**. This could stimulate investment in AI practices that prioritize safety and social welfare. The challenge that could arise here lies in establishing clear and measurable criteria for determining what constitutes "ethical AI" and also how it will be evaluated for incentive eligibility, given the complexity and rapidly evolving nature of the field. Another relevant aspect to contemplate is the existence of an equitable distribution of incentives and that they are accessible to a wide variety of actors, including startups and non-profits. This would be crucial to avoid that only large corporations benefit from these incentives.

- **IMPLEMENT EDUCATION AND TRAINING PROGRAMS ON ETHICAL PRINCIPLES IN THE DEVELOPMENT AND USE OF AI** for developers, healthcare professionals and the general public. Awareness and training on these issues is key to promoting a responsible approach.

- **ESTABLISH A REAL-WORLD PERFORMANCE MONITORING SYSTEM TO DETECT POTENTIAL PROBLEMS AND ENSURE CLEAR PROTOCOLS FOR RESPONDING TO INCIDENTS RELATED TO THE MISUSE OR FAILURE OF IA SYSTEMS** (21,22). This type of continuous monitoring allows overseeing the

performance of AI technologies in their actual application environment, which helps to identify unexpected changes or emerging risks early. By having a system that evaluates performance in real time and with rapid action protocols, it is possible to mitigate damage and improve safety, thus reinforcing confidence in the use of AI in the healthcare sector.

- **CREATE AN ACCESSIBLE DATABASE THAT COMPILES DOCUMENTED BUGD AND FAILURES IN AI SYSTEMS** functioning as a knowledge repository for developers and implementers. This repository would facilitate the sharing of experiences and lessons learned, allowing the AI community to identify patterns of errors and develop more effective prevention strategies. This tool would promote a culture of continuous learning and collaborative improvement in the field of AI.

06. SUMMARY DIAGRAM

ESSENTIAL PILLARS OF A REGULATORY FRAMEWORK FOR IA IN HEALTH

PILLARS FOR REGULATORY FRAMEWORK FOR IA IN HEALTH

- ETHICAL PRINCIPLES
- PRECISE DEFINITIONS
- PREVENTION OF BIAS
- HUMAN SUPERVISION
- RESPONSIBILITIES AND ROLE ASSIGNMENT
- CERTIFICATION OF STANDARDS
- MONITORING AND EVALUATION
- UPDATE

HARD LAW + SOFT LAW

- SINGLE LAW
- SPECIFIC REGULATIONS BY SECTOR

- CODES OF CONDUCT
- STANDARDS CERTIFICATION
- ETHICAL GUIDELINES
- SELF-REGULATORY AGREEMENTS
- ALIGNMENT OF INTERNATIONAL ETHICAL FRAMEWORKS
- REGULATORY SANDBOX

COMPLEMENTARY INTERVENTIONS

- Research in legal and social ethical implementations
- Incentives for the development of ethical and responsible technologies
- Education programs on ethical principles
- Real-world monitoring system
- Database with errors and failures

07. CONCLUSIONS

A particular challenge facing the regulatory universe, and one that deserves deep reflection, is the need to frame a technology that is not static, but evolves continuously and at an accelerated pace. AI, by its very nature, is constantly developing and emerging at a speed that current regulatory structures may have difficulty keeping up with. This dynamism presents an unprecedented challenge: **regulating a perpetually changing technology without stagnating its innovative potential or compromising ethical and safety principles**.

This paper identifies and provides some adaptable and pragmatic options to ensure that AI regulation can keep up with the pace of technological innovation, thus preventing regulations from becoming obsolete or unnecessarily restrictive.

Through the implementation of these various regulatory alternatives, the aim is to **establish a framework that not only addresses the current situation, but is also prepared for future developments, ensuring that AI in the health sector moves forward in accordance with the principles of equity, transparency and accountability.**

This paper highlights the importance of thoughtful and structured regulation that allows AI to flourish and effectively serve society, while ensuring the comprehensive protection of the rights and safety of individuals. The proposed **"menu of options"** aspires to be not only a set of recommendations, but also an **invitation for dialogue and reflection on how we can collectively guide the development of technology in a way that truly benefits humanity.**

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