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WHY IS IT IMPORTANT TO REGULATE ARTIFICIAL INTELLIGENCE IN THE HEALTHCARE SECTOR?

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CONTENT

KEY MESSAGES

- In the digital age, artificial intelligence (AI) plays an increasingly significant role in various sectors, and healthcare is no exception. However, the integration of AI in this sector cannot be neglected or left to chance, due to the extremely sensitive nature of health data and the decisions made from it.

- Regulation plays a vital role in standardizing practices and procedures in the healthcare sector, ensuring that artificial intelligence (AI) technologies meet quality and safety criteria, and promoting responsible innovation.

- The lack of regulatory harmonization not only complicates the implementation of AI within a country, but also harms development internationally, generating additional obstacles for companies seeking to operate globally. International cooperation and the adoption of common standards are essential to facilitate the expansion of technological innovations.

- There is no single path to regulate AI in the healthcare sector; options range from rigid laws (hard law) to flexible approaches (soft law). Each country should choose the option that best suits its context and idiosyncrasies, including a mixed system.

- Hard law provides mandatory security and effectiveness in the use of AI, but parliamentary times generate the risk that the law will become outdated in the face of the rapid advance of technology.

- Soft law, with its flexibility, allows for rapid adaptation to new technologies and methods, encouraging constant innovation. However, their lack of mandatory use can result in inconsistent enforcement and compromise patient safety.

- A hybrid regulatory design, combining hard law with soft law, ensures that fundamental ethical principles are kept inviolable and consistent through firm law, while technical and operational details can be flexibly and efficiently adapted by competent agencies.

- In federal countries like Argentina, Brazil, and Mexico, regulatory coordination between the national government and provinces/states is crucial to avoid barriers that hinder innovation in AI in healthcare and to prevent further legal fragmentation. Without adequate coordination, both public and private initiatives could face a variety of different regulations, increasing compliance costs and delaying technology adoption.

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PRESENTATION

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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 programs 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 serie of documents on AI is 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 document analyzes the need to establish a regulatory framework for AI in health, highlighting the importance of ensuring the quality and safety of the technologies implemented. Regulation is vital to avoid risks associated with errors in algorithms and to ensure that innovations are carried out responsibly and ethically. The integration of AI into health must consider local contexts and human ethical principles, and an ongoing dialogue between technology and health professionals is required to build public trust and ensure equitable distribution of benefits.

In addition, the document states that a hybrid regulatory approach, combining rigid laws (hard law) and flexible approaches (soft law), would be ideal to adapt to rapid technological evolution without compromising patient safety. Regulatory coordination, especially in federal countries, is crucial to avoid legal fragmentations that can hinder innovation and increase compliance costs. International cooperation and harmonization of standards are also essential to facilitate the global expansion of AI technologies in health, promoting an attractive investment environment and stimulating regional economic growth.

01. INTRODUCTION

In the digital age, artificial intelligence (AI) plays an increasingly significant role in various sectors, and healthcare is no exception. However, the integration of **AI in this sector cannot be neglected or left to chance, due to the extremely sensitive nature of health data and the decisions made from it**.

Health data is more than just numbers, it represents human stories, personal contexts, and states of vulnerability that deserve exceptional protection. Critical decisions made in this area, often life-or-death, require a high level of attention and care. The potential of AI to transform the healthcare sector is immense, but without the right safeguards, the risks can outweigh the benefits. As we adopt these advanced technologies, it is essential to consider the legal and societal implications of their implementation.

Undoubtedly, **regulation plays a vital role in standardizing practices and procedures**. In a field as critical as healthcare, it will be extremely important to build consistency in the ways AI technologies are developed, implemented and used. **Regulations help establish common standards, ensuring that all technologies meet the same quality and safety criteria, while encouraging innovation and technological advancement**.

In addition, an adequate regulatory framework can foster **responsible innovation**, establishing clear guidelines that incentivize companies to develop AI technologies that are not only effective but also safe and ethical. This certainly creates an environment where **innovation can thrive without compromising patient safety and well-being**.

In addition, the regulatory frameworks that are developed must take into account human supervision in decision-making processes involving AI. Humans must play a central role in this paradigm, not only to ensure the accuracy of AI-proposed diagnoses and treatments but also to ensure the accuracy of AI-proposed diagnoses and treatments. **Preserving the essence of medical practice as an intrinsically human act that values empathy, ethical judgment, and respect for patient autonomy** [1]**.**

The **healthcare sector has an inherent global reach**, as solutions developed in one region can be easily implemented in another. Regulation **thus plays a key role in creating universal standards that promote international cooperation and facilitate the exchange of AI-based health technologies**. This uniformity is especially important in a world where technological advancement is rapidly removing geographical barriers, making collaboration and adoption of health innovations more accessible globally.

For these reasons, the regulation of AI in the healthcare sector is not only a necessary measure: it is an essential responsibility to ensure that the integration of this technology is done ethically and safely. Achieving flexible and well-conceived regulation will be crucial for AI to reach its transformative potential without compromising the fundamental ethical values of our society.

02. WHAT IS A REGULATORY FRAMEWORK AND WHAT IS ITS USE?

A regulatory framework is a **set of laws, rules, regulations, and other official publications that govern and regulate the behavior of individuals, companies, and other organizations**[2]**.** This framework is established to ensure that activities within the sector are carried out ethically, safely, and efficiently, protecting public and private interests. Calling a set of regulations a "framework" helps to convey the idea of an organized structure, with clear boundaries, but also with the ability to integrate and relate various components that, together, form a complete and understandable regulatory system.

So, a regulatory framework works through the creation of clear rules, but also through their effective implementation, the promotion of voluntary compliance, the application of sanctions, transparency, and continuous improvement. The laws[3], created by parliaments or congresses, establish the general principles, while the regulations[4], developed by regulatory agencies[5], detail and implement those standards in practice.

The following are the elements of a regulatory framework:

1. CREATION OF LAWS AND REGULATIONS	• **Laws:** they are created by parliaments or congresses. They are formal rules of mandatory compliance and are approved by elected representatives. Laws establish the principles and general rules that must be followed within a sector. • **Regulations:** these are developed by regulatory agencies or executive authorities that have the authority to issue more specific rules based on the laws. These agencies may include government bodies such as ministries, departments, or specialized commissions.
2. IMPLEMENTATION AND SUPERVISION	To operate, regulated entities obtain licenses and permissions that certify their ability to meet the standards set by laws and regulations. To ensure compliance with regulations, regulatory agencies supervise and monitor through inspections and audits.
3. VOLUNTARY COMPLIANCE PROMOTION	In addition to mandatory standards, guidelines and best practice instructions are issued to help organizations comply with regulations. Furthermore, education and training programs provide the necessary knowledge to operate within the regulatory framework.
4. SANCTIONS APPLICATION	In case of non-compliance, the authorities can impose fines, penalties or close operations. They may also require corrective actions to resolve issues and prevent future incidents. Penalties are defined in both specific laws and regulations.
5. TRANSPARENCY [6] AND ACCOUNTABILITY [7]	Regulated organizations must submit regular reports to demonstrate compliance. Information on inspections and sanctions is made public to promote transparency and public oversight.
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. EVALUATION AND CONTINUOUS IMPROVEMENT	Periodic evaluations determine the effectiveness of regulations. Based on these analyses, adjustments are made to continuously improve the regulatory framework and adapt to new challenges.

03. WHY IS IT NECESSARY TO CREATE A REGULATORY FRAMEWORK FOR AI IN THE HEALTHCARE FIELD?

At the center of any ethical consideration is human dignity. AI can deeply impact our lives, from medical decisions to essential services access. **A regulatory framework ensures that these technologies respect and protect each individual dignity, preventing abuses and ensuring that people are not treated merely as data or numbers**[8].

If not properly monitored, AI has the potential to perpetuate and amplify existing biases[9]. Algorithms can inadvertently discriminate based on ethnicity, gender, age, or other factors[10]. For these reasons, a regulatory framework **establishes standards to assess and mitigate these biases, ensuring fair and equitable decisions**.

On the other hand, AI often functions as a "black box"[11], whose internal processes are not understandable to developers, and even less so to users. A regulatory framework can **demand transparency in how AI systems work**, and who is responsible for their decisions and actions. This clarity is essential for accountability and for people to be able to trust the technologies that impact their lives.

Personal autonomy is a crucial ethical value [12]. People need to have control over how their data is used and how technologies influence their lives. A regulatory framework can **ensure that individuals have the ability to give or withdraw their consent for the use of their data, and to understand decisions made** by AI systems, preserving their autonomy in this regard.

It is important to note, moreover, that AI has the potential to cause harm if not managed properly. From autonomous vehicles to medical diagnostics, errors in AI systems can have serious consequences. A regulatory framework establishes **safety standards to prevent failures and protect people from possible harm**. Safety is a fundamental ethical principle, and regulation is crucial to ensure that AI is used safely.

Technology must serve the common good and promote social justice, and AI can deliver significant benefits, such as improvements in healthcare and energy efficiency. However, these benefits must be distributed equitably. A regulatory framework **can promote the development of AI that benefits the entire society, not just a privileged few**. This ensures that technology contributes to greater social justice and collective well-being.

In addition, without regulation to oversee and guide the use of AI in health, there is a risk that this technology will favor certain groups over others, exacerbating disparities in access and quality of health care[13]. The development of these standards can help ensure that all individuals, regardless of their social or economic background, have equitable access to the benefits that AI can offer in the healthcare field.

The ability to make informed decisions about our own body and health is a central aspect of our personal autonomy. **A regulatory framework can ensure that patients retain control over their health decisions and that AI is used as a tool to support, rather than replace, individual autonomy.**

These considerations underscore the need for a regulatory framework that guides the development and implementation of AI in the healthcare field, ensuring that its benefits are realized ethically and fairly.

04. WHAT TOPICS SHOULD WE REGULATE?

As mentioned in the previous sections, there are numerous aspects of people's lives that AI is already impacting, and for which regulation can be proposed to enable the protection of individuals while also fostering innovation.

One of the main aspects is the **use of data** in AI. Data is the fuel that drives AI algorithms, and its collection and use must respect people's privacy and autonomy. For this reason, it is important to promote regulations that ensure that individuals give informed consent for the use of their data, and that they have control over how this data is collected, stored, and used. This protects personal autonomy and prevents people from being exploited for commercial interests.

Another aspect to consider is transparency **in AI algorithms**. As previously mentioned, AI systems often function as "black boxes," whose internal processes are not understandable to users. Regulations that are developed should require AI developers to clearly explain how their algorithms work and how decisions are made.

Along the same lines, **equity and non-discrimination** should be core principles guiding the regulation of AI. Algorithms can perpetuate and amplify existing biases, which can result in unfair and discriminatory decisions. Regulations should establish standards to assess and mitigate these biases, ensuring that AI treats all individuals fairly and equitably.

Security is another fundamental aspect to regulate. AI systems must be safe and reliable, especially when used in critical contexts such as healthcare, so regulations must establish safety standards to prevent failures and protect people from potential harm.

Ensuring the safety of AI is an ethical imperative to avoid negative consequences and protect people's well-being.

Similarly, **liability is an essential variable in AI regulation**. For this, it is critical to define who is responsible when an AI system causes harm or malfunctions, and regulations must establish clear mechanisms for accountability, ensuring that there are consequences for those who develop and implement AI systems. This clarity of accountability is necessary for justice and the protection of the rights of affected individuals.

In short, AI should be used to promote public welfare, solve social problems, and improve people's quality of life. Developing **regulations that encourage this responsible use ensures that technology serves the interests of the entire society, not just commercial interests.**

05. WHAT IS THE IMPACT OF THE NON-REGULATION OF AI IN THE HEALTHCARE FIELD?

AI, in its current state and in the way it is understood and developed up to today, does not have consciousness or its own will. Therefore, the concept of "ignoring" ethical principles would imply that such AI possesses a level of autonomy and understanding that present-day AIs do not yet possess. However, there are ways in which an AI can act in a manner that appears to conflict with the ethical principles it was "trained" or programmed to follow. Here are some examples:

1. Errors in the design or implementation in health: AI algorithms designed for healthcare applications, such as those that diagnose diseases or recommend treatments, should be handled with extreme caution. A flawed design or implementation could not only promote harmful outcomes, but also put lives at risk. A relevant example is a joint study between STAT[14] and the Massachusetts Institute of Technology (MIT) which revealed that the EPIC system's health algorithm[15], used to predict the risk of sepsis in patients in the U.S., suffered a significant decline in efficacy over 10 years. Originally, the algorithm had an effectiveness (measured as area under the curve, or AUC) of 0.73, but this decreased to 0.53. The reasons for this decline include changes in the hospital coding system, an increase in the diversity and amount of patient data, and changes in medical practices. Once the algorithm was implemented, this deterioration was not adequately monitored, which increased the risk of making incorrect medical decisions and causing harm to patients. This

case underscores the critical need to regularly audit and update AI algorithms in the medical field to maintain their effectiveness and safety over time[16].

2.Limitations in understanding AI in the health context: Medicine is a complex field, where human clinical judgment plays a crucial role. An AI that operates with limited understanding, based only on the data and instructions it was trained with, could overlook important nuances in patient care. This becomes especially critical in situations where symptoms may be ambiguous or where various conditions may present in a similar manner. An example of this was revealed by the study conducted by Lauren Oakden-Rayner's team[17] when they conducted an audit of an AI designed to detect hip fractures. The audit revealed that the AI showed a decrease in its sensitivity[1] at a pre-specified operating point and evidenced several "failure modes" under particular conditions. In an interview for "The Lancet Digital Health", Oakden-Rayner stressed that some errors in AI were so obvious that even a "non-expert" would recognize them, a situation that could considerably diminish the confidence of doctors and patients in this technology[18].

3. Evolution of AI through learning and decision-making: AIs that learn and evolve in the context of health could develop strategies that maximize what that AI considers to be "efficiency," without fully considering the patient's well-being. This is directly linked to the fact that AI systems operate based on objectives that have been assigned to them. An example of this is the case of Obermeyer's study [19], which highlights that the algorithm analyzed uses patients' past healthcare expenditures as an indicator to predict who might need intensive medical care in the future. However, this method introduces a racial bias because not all groups have the same access to health services. In particular, African American patients tend to spend less on health care, not because they don't need care, but because they face more significant barriers to accessing it. As a result, although two patients (one African American and one Caucasian) may have similar health needs, the African American patient's medical cost history could be lower, leading the algorithm to incorrectly conclude that this patient is in better health and needs less care. This is problematic because it perpetuates inequities in healthcare and can result in some patients not receiving the treatment or preventive care they truly need.

4.AI not adapted to local contexts: Ethical principles and regulations in medicine can vary significantly between cultures, jurisdictions, and individual situations. An AI that does not adapt or cannot consider these changing contexts could offer recommendations that are inappropriate or even harmful in certain situations. We could cite the example of the case of Brazil, which used AI to diagnose COVID-19 using CT scans[20]. The tool used was RadVid-19, developed by Huawei and Siemens, which facilitated the rapid diagnosis and treatment of critical patients. The problem was that the AI was trained on datasets containing images of patients from China and Europe that did not capture the diversity of the Latin American target population, which ended up causing a decrease in the effectiveness of the algorithm

[1] The ability of the diagnostic test to detect sick individuals.

for populations in Latin America due to genetic and phenotypic differences that affected the interpretation of medical images.

In addition to these concrete and current examples of the possible ethical conflicts of AI, there is a theoretical concern about an AI that acquires sufficient autonomy to make its own decisions and that "ignores" the ethical principles with which it was trained. This debate takes place within the framework of the possible existence of superintelligent AI[21][2] or an AI that is known as a "general type"[22], which does not yet exist. However **it will be necessary to be attentive to the evolution of this technology, in order to optimize the management of the risks associated with a potentially superintelligent AI that will require safeguards and control mechanisms different from those that exist.**

It is therefore necessary to establish clear guidelines in regulations to guarantee human supervision. The effective integration of AI into healthcare requires a **"continuous dialogue" between technology and healthcare professionals, to ensure that clinical decisions are always focused on the patient's well-being.**

Through careful design, rigorous validation of AI systems in health, and the **inclusion of human medical judgment**, we will be able to move towards an integration of AI that improves healthcare, while maintaining the highest standards of safety, fairness, and ethics. This approach is not only critical to gaining the trust of the public and health professionals[23], but also to ensure that the benefits of AI are distributed equitably across society.

Could an AI deviate from the ethical purpose for which it was trained? The answer is yes, it can happen. Although an AI has no consciousness or intention of its own, its actions may deviate from initial ethical principles due to limitations in its design, interpretation of data, or changes in the clinical context. Moreover, while the concern around superintelligences operating completely autonomously is still theoretical and does not correspond to current AI capabilities, this future scenario further underscores the need for continuous monitoring and regular updates. Therefore, **it is essential to ensure that any AI system, current or future, remains aligned with established ethical and safety objectives, especially in a field as critical as medicine and health.**

[2] Bostrom calls "superintelligence" (also known as general or strong AI), understood as a system of artificial general intelligence that could exceed all human cognitive capabilities in virtually any discipline.

06. WHAT REGULATORY PATHS SHOULD WE TAKE?

Here the question is settled between adopting traditionally rigid parliamentary regulations, the **hard law**[24]**,** compared to more flexible approaches such as white books or ethical guidelines, the **soft Law**[25].

The truth is that both options present different challenges and opportunities that need to be carefully examined.

Parliamentary **laws or hard laws** are designed to provide a solid legal framework that guarantees the safety and efficacy in the use of AI in health, in addition to being mandatory. This approach is ideal for protecting patients and ensuring that new technological developments are implemented responsibly. In practice, however, the rigidity of a law's text could hinder innovation. The pace of AI advancement is exceptional, and legislative cycles can't always keep up. This poses a risk that legislation may become outdated almost as soon as it is enacted, thus limiting the ability of the health sector to use the most advanced and potentially most effective technologies.

On the other hand, the **soft law**[26], offers the flexibility to adapt quickly to new emerging technologies and methods, enabling a more agile AI implementation in real-world practice, adapting to the changing needs of the field and promoting a culture of constant innovation. However, their non-enforceability can result in inconsistent enforcement and non-compliance, which in turn could compromise patient safety.

In healthcare, the need to ensure safety and efficacy is paramount, as AI-based decisions can have direct and significant consequences on patients' lives and well-being. **The rigidity of hard law ensures that there are clear mandatory rules that ensure that patients are protected from the rapid incorporation of potentially risky technologies.**

However, the field of health is also characterized by its rapid evolution in terms of diagnosis and treatments technologies. AI is constantly developing, introducing new capabilities that may require agile regulatory adaptation that hard law cannot provide. This is where **soft law plays a crucial role, allowing for quick and flexible adaptation to new technologies and emerging methods without sacrificing the necessary rigor in a medical context.**

Given this scenario, it is clear that the health sector will require a regulatory framework. For this reason, when asked which regulatory path we should take, **a hybrid approach that**

combines the strength of hard law with the adaptability of soft law would be the appropriate answer.

A regulatory scheme for AI in health should seek a balance between rigidity and flexibility to adapt to the dynamic nature of the technology without losing the requirement of obligation.

Fundamental ethical principles, which are considered untouchable, such as the human-centric approach, non-maleficence, beneficence, transparency, human autonomy, equity, accountability, among others, could be rooted in rigid legislation. This law would establish a solid and permanent framework that ensures that all AI developments and applications in health adhere to these essential values, which do not tend to be changeable.

Another aspect that should be framed in a law is **to grant clear powers of jurisdiction to regulatory agencies designated in the law or already in place.** This is essential, understanding the role that legislation plays in this process. The law acts as the foundation that grants and delimits the competences of these agencies, ensuring that they have indisputable legal authority to execute their functions. The law, when passed by a legislative body, provides this framework, endowing agencies with explicit powers, ensuring that the agency not only has the necessary authority to act, but also operates within a clear legal framework that prevents ambiguity and reinforces public confidence in its ability to regulate. In addition, legal backing strengthens the agency in the face of potential legal challenges or disputes over its jurisdiction and decisions, providing a solid foundation for its operation and decision-making.

By giving agencies explicit powers, the law will allow them, for example:

a) Define technical terms: establish and update technical definitions, much more quickly and easily than if they were within a law.

b) Determine the risk classification criteria: set the standards for evaluating AI systems according to a defined scale of high, medium or low risk, adapting and evolving more quickly than if they were within a law.

c) Specify documentation requirements: determine what documentation is necessary for the submission and approval of AI systems, ensuring that there is transparency and accountability in the evaluation and approval processes. This would allow these requirements to be modified as innovation advances.

In short, this approach would allow the regulatory framework to adapt quickly to technological changes, but with primary respect for human beings. Agencies, being at the forefront of technology, can modify and update standards and criteria with much more agility than the traditional legislative process, which is generally slower and less receptive to rapid technological evolution. In this way, the agencies will act as specialized entities capable of

responding efficiently to emerging challenges and ensuring that regulation keeps up with the development of AI.

This regulatory design ensures that fundamental ethical principles are kept inviolable and consistent through firm law, while technical and operational details can be flexibly and efficiently adapted by competent agencies. Thus, responsible innovation would be promoted and the integrity and rights of users and patients in the health context would be protected, adapting regulations to the continuous evolution of AI.

In this sense, **mechanisms for periodic and adaptive review of regulations could be implemented**, which allow a dynamic response to rapid changes in technology and medical practices. Thus, the hybrid regulatory model would foster an environment of constant improvement and innovation within the health sector.

It should also be noted that, if we look at global experiences[26], 70% of the countries that have allocated resources and developed soft law programs in AI are located in Europe, Central or East Asia and the Pacific, which indicates that these regions are leaders in the dedication of resources to the regulation of AI through the use of soft laws and that countries with greater economic resources are more involved in advancing in this line.

In this way, then, it is evident that developing a hybrid model is among the most flexible and at the same time most innovative and safe options to advance AI regulation in the region.

07. REGULATORY CHALLENGES FOR FEDERAL COUNTRIES

In Latin America and the Caribbean, the fragmentation of health systems is a significant challenge that affects the effectiveness and efficiency of health service delivery. This fragmentation manifests itself in a lack of coordination and organization between the different levels of care, resulting in duplication of services, conflicts between different treatment schemes, and, in many cases, unequal access to medical care. This problem is exacerbated in countries with federal structures such as Argentina, Brazil, and Mexico, where the coexistence of national and provincial/state regulations can further complicate the integration of health services.

The implementation of AI in the healthcare sector introduces an additional layer of complexity to this already challenging landscape. The expansive nature of AI technology, which knows no regional or international boundaries, requires the development of coherent and coordinated regulation since, if **there were a disparity in regulation at the**

subnational level in countries such as Argentina, Brazil and Mexico, this could create significant barriers to innovation and efficient implementation of AI solutions in health.

Without effective coordination, companies developing these technologies could face a variety of local regulations that could increase costs and delay or impede the adoption of new innovations. For example, standards for the validation and testing of AI algorithms could vary significantly from one province/state to another, making it challenging to implement safe and effective AI solutions in the healthcare sector. This lack of harmonization could not only negatively impact technological development, but could also affect equity in access to advanced health technologies, perpetuating or even exacerbating existing inequalities in access to healthcare.

Therefore, it is necessary to **promote an integrated and coordinated approach at both subnational and international levels to develop a regulatory framework that facilitates the adoption and efficient use of AI in the health sector**[23].

In addition, companies are more likely to invest in technological development when they know that regulations are consistent and stable, so **a harmonized regulatory environment can attract foreign investment and stimulate regional economic growth by creating a more attractive and competitive market.**

In this way, it is observed that, both at the subnational level in federal countries and at the international level, regulatory coordination is essential to foster an enabling environment for innovation in AI in health and economic development.

08. CONCLUSIONS

Let's make an analogy with the world of sports. To play football, for example, you need to know and follow a set of well-defined rules. These rules state which actions are allowed and which are not and how disputes are resolved during the game. Without these rules, the game would be chaotic. Football rules not only provide a structure for the game, but also ensure that anyone, anywhere in the world, can understand and participate in the sport uniformly without needing to redefine the rules each time, making the process easier and homogenised.

Similarly, in the health sector, which by its nature is already managed with international protocols and standards, the existence of clear rules to implement AI in this sector is essential. The rules that are established will help determine what practices

are acceptable, how patient data should be handled, how AI systems should be validated and tested, among other aspects.

Just as uniform rules in sports allow the game to be played consistently worldwide, in the healthcare sector, a uniform set of regulations will enable AI to be used consistently and safely across different regions and contexts. This uniformity will also be able to make it easier to certify new AI systems, as everyone would be aware of the rules and standards they must comply with. In addition, if these rules are in line with those developed by international organizations, it will contribute to greater harmonization and global acceptance of the AI systems in health that are developed in our region.

Importantly, just like in football, where the rules can be adjusted and evolved to improve the game and adapt to new circumstances, in the healthcare sector, AI regulations should also be flexible and adaptive. This is where the reflection comes into play regarding what type of regulatory scheme should be used: hard law (rigid laws), soft law (more flexible guidelines) or a hybrid scheme. This choice will depend on the context of the country, the roadmap that each one analyzes to draw up to develop their regulatory frameworks, and the legislative idiosyncrasy[3] that predominates.

Undoubtedly, establishing a regulation for AI in the health sector can foster trust and promote innovation. However, we must be aware that we are dealing with a rapidly evolving technology that presents unique challenges in the regulatory field. This context requires not only interdisciplinary collaboration, but also a creative and adaptive approach. This underscores the need to move away from traditional approaches and adopt new perspectives and methodologies to address today's challenges.

[3] Legislative idiosyncrasy refers to the characteristics, traditions, practices, and approaches that distinguish the law-making process in a particular country or jurisdiction. This idiosyncrasy is influenced by historical, cultural, political, and social factors, and can determine aspects such as the rigidity or flexibility of laws, the role of legislative institutions, citizen participation in the legislative process, and the relationship between different branches of government.

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