Cadernos Ibero-Americanos de Direito Sanitário
Cuadernos Iberoamericanos de Derecho Sanitario
ISSN: 2358-1824

Article

The Legal Framework for Science, Technology and Innovation and its role in the digital transformation of the Unified Health System

O Marco Legal de Ciência, Tecnologia e Inovação e seu papel na transformação digital do Sistema Único de Saúde

El Marco Legal de Ciencia, Tecnología e Innovación y su papel en la transformación digital del Sistema Único de Salud

Mariana Hamú Ribeiro[1]
Ministério da Saúde, Brasília, DF.
https://orcid.org/0009-0008-0567-9020
mariana.hamu@saude.gov.br

José Rafael Cutrim Costa[2]
Fundação Oswaldo Cruz, Brasília, DF.
https://orcid.org/0000-0002-8634-3121
rcosta27@icloud.com

Abstract

Objective: To analyze the role of the Legal Framework for Science, Technology, and Innovation in the digital transformation of the Brazilian Unified Health System, highlighting the legislative changes introduced by Constitutional Amendment No. 85/2015, Law No. 13,243/2016, and Decree No. 9,283/2018. **Methodology:** An exploratory documentary methodology with a qualitative approach was used. Data collection was carried out through official sources, searching government portals, Google Scholar, and the Virtual Health Library. The findings were systematized in comparative tables, emphasizing the original legal provisions and their modifications. Descriptive analysis enabled the evaluation of the effects of legislative changes on the health sector. **Results:** The results show progress in process digitalization, intersectoral cooperation, and the adoption of technologies such as artificial intelligence, while also identifying persistent challenges such as regulatory harmonization and ensuring equity in access to digital benefits. **Conclusion:** The Legal Framework for Science, Technology, and Innovation represents a strategic project for the Unified Health System, whose effectiveness depends on continuous updates, capacity-building for managers, and social coordination, thus transforming innovations into concrete improvements in service quality and system sustainability.
Keywords: Unified Health System; Technological Innovation; National Science, Technology and Innovation Policy.

Resumo

Objetivo: analisar o papel do Marco Legal de Ciência, Tecnologia e Inovação na transformação digital do Sistema Único de Saúde, destacando as alterações legislativas introduzidas pela Emenda Constitucional nº 85/2015, Lei nº 13.243/2016 e Decreto nº 9.283/2018. **Metodologia:** utilizou-se uma metodologia documental exploratória, de base qualitativa. A coleta de dados foi feita por meio de

[1] Bachelor of Law, Faculdade Projeção, Brasília, DF, Brazil. Senior Legal Analyst, Ministério da Saúde, Brasília, DF.
[2] Master's Degree in Public Health Policy, Fundação Oswaldo Cruz, Brasília, DF, Brazil.

fontes oficiais, com busca nos portais governamentais, *Google* Acadêmico e Biblioteca Virtual de Saúde. Os achados foram sistematizados em quadros comparativos, destacando os dispositivos legais originais e suas modificações. A análise descritiva permitiu avaliar os efeitos das mudanças legislativas no setor de saúde. **Resultados:** os resultados demonstram avanços na digitalização de processos, cooperação intersetorial e adoção de tecnologias como inteligência artificial, além de apontarem desafios persistentes, como a harmonização regulatória e a garantia de equidade no acesso aos benefícios digitais. **Conclusão:** O Marco Legal de Ciência, Tecnologia e Inovação representa um projeto estratégico para o Sistema Único de Saúde, cuja efetividade depende de atualizações contínuas, capacitação de gestores e articulação social, para assim transformar inovações em melhorias concretas na qualidade do atendimento e na sustentabilidade do sistema.
Palavras-chave: Sistema Único de Saúde; Inovação Tecnológica; Política Nacional de Ciência, Tecnologia e Inovação.

Resumen

Objetivo: analizar el papel del Marco Legal de Ciencia, Tecnología e Innovación en la transformación digital del Sistema Único de Salud de Brasil, destacando las modificaciones legislativas introducidas por la Enmienda Constitucional nº 85/2015, la Ley nº 13.243/2016 y el Decreto nº 9.283/2018. **Metodología:** se utilizó una metodología documental exploratoria, de base cualitativa. La recolección de datos se realizó mediante fuentes oficiales, con búsquedas en portales gubernamentales, Google Académico y la Biblioteca Virtual en Salud. Los hallazgos se sistematizaron en cuadros comparativos, destacando los dispositivos legales originales y sus modificaciones. El análisis descriptivo permi etióvaluar los efectos de los cambios legislativos en el sector salud. **Resultados:** los resultados demuestran avances en la digitalización de procesos, la cooperación intersectorial y la adopción de tecnologías como la inteligencia artificial, además de señalar desafíos persistentes como la armonización regulatoria y la garantía de equidad en el acceso a los beneficios digitales. **Conclusión:** El Marco Legal de Ciencia, Tecnología e Innovación representa un proyecto estratégico para el Sistema Único de Salud, cuya efectividad depende de actualizaciones continuas, capacitación de los gestores y articulación social, para así transformar las innovaciones en mejoras concretas en la calidad de la atención y en la sostenibilidad del sistema.
Palabras clave: Sistema Único de Salud; Innovación Tecnológica; Política Nacional de Ciencia, Tecnología e Innovación.

Introduction

Despite the growth in public health services resulting from the expansion of the system, access networks, and public policies in general, users' perception of the quality of these services has not kept pace with this evolution[1]. During the COVID-19 pandemic, the consumption of public services increased by 10.3%[2] and the supply of jobs in the area expanded by 59.8%. Studies indicate that approximately 71% of Brazilians use the Unified Health System (SUS), which has established itself as the main gateway to health services[3].

However, user opinions show that the SUS has shortcomings in the methodologies and procedures applied in the implementation of public health policies[4]. At the same time, social demand for services that keep pace with changes in the contemporary world has encouraged the restructuring of care and administrative practices, promoting the modernization of actions and the adoption of innovative approaches, including technological ones[1,4].

The spread of Information and Communication Technologies (ICTs) has changed business models, consumption, and access to services in various sectors. In the field of public health, the incorporation of digital resources, such as the Internet of Things (IoT) and Artificial Intelligence (AI),

has stimulated institutional changes, inspired by successful experiences observed in countries with higher service quality indices[2,4].

The Legal Framework for Science, Technology, and Innovation (CT&I), created by Law Nº. 13,243/2016[5], is a set of rules that aims to promote interaction between scientific research, technological development, and the needs of society, with the goal of stimulating innovation in the country. The Legal Framework establishes guidelines to encourage research, innovation, and technology transfer, seeking to integrate different sectors of society, such as universities, companies, and public agencies, for the development of innovative solutions. The legislation, therefore, acts as a facilitator for the implementation of new processes and technologies, both in the private and public sectors, aligning itself with contemporary social and economic demands[1].

In relation to public health, the Legal Framework for ST&I has proven to be a relevant instrument for the advancement of innovative technologies in the SUS, promoting the modernization of care and administrative practices. The implementation of new technologies has transformed care and management models, allowing for greater efficiency and effectiveness in the provision of services.

The legislation has also helped to overcome bureaucratic obstacles that hinder the adoption of innovations, in addition to fostering collaboration between the public and private sectors, which is essential for the development of technological solutions applied to health[6]. In addition, they highlight the updating of legal provisions and the convergence between the health sector and technological innovations[1].

Given this scenario, the overall objective of this study is to analyze the role of the Legal Framework for ST&I in the digital transformation of the SUS, highlighting the legislative changes introduced by Constitutional Amendment Nº. 85/2015, Law Nº. 13,243/2016, and Decree Nº. 9,283/2018.

Methodology

This research adopted an exploratory documentary methodology[7,8,9] for the collection and analysis of data related to the norms that make up the legal framework of ST&I and its application in the context of the SUS, using a qualitative approach[8,9].

Initially, the main regulations and legislative changes were identified by consulting official sources, such as the Federal Official Gazette, government websites, and specialized legal databases, as well as searching for articles and materials on government websites. The search was conducted using Google, Google Scholar, the Virtual Health Library, and official Federal Government websites. The selected portals were consulted based on the reliability of the information, as they are reliable databases and provide information that is closest to reality.

Data collection involved searching for up-to-date and relevant information, ensuring that all relevant laws and amendments were considered. To this end, the following keywords were used: “Legal Framework for Science, Technology, and Innovation,” “SUS,” “technological innovation,” and “legal norms,” which allowed for the location of documents describing both the creation and changes to legal provisions.

The document *corpus* consisted of 12 norms, selected based on their relevance to the evolution of the regulatory framework and their impact on the structure and functioning of the public health sector. As a methodological choice and considering that this is a normative analysis, laws repealed after the publication of Law Nº. 13,243/2016 were replaced by the norms currently in force.

After identifying the norms, the documents were organized chronologically to follow the temporal sequence of legislative changes, facilitating the descriptive analysis of the practical effects of the changes on the public health sector. The data were systematized using comparative tables, highlighting the original provisions and their respective modifications.

The descriptive analysis consisted of interpreting the legal provisions collected, aiming to identify the changes implemented and the effects of these changes on the structure and operation of the SUS. This process involved critically reading and comparing the legal texts, allowing for an assessment of the impacts of technological innovations on the management and provision of public health services. The study also considered the contexts in which the regulations were enacted, relating technological advances to the needs and demands of the health sector.

Results and discussion

Based on the identification and analysis of the regulations dealing with the Legal Framework for Science, Technology, and Innovation in the digital transformation of the SUS, an overview of the main regulations that underwent legislative changes during the period studied was verified on the Federal Government Portal and collected for the purpose of this article (Table 1).

Table 1. Regulations selected from the Federal Government Portal for analysis in 2024

Regulation	Date of Publication	Title of the regulation	Summary
Law Nº. 8,010	03/29/1990	Import Law for Research	Provides for the importation of goods intended for scientific and technological research.
Law Nº 8,032	04/12/1990	Tax Legislation Law	Amends provisions of tax legislation.
Law Nº 8,745	12/09/1993	Temporary Hiring Law	Provides for fixed-term contracts to meet temporary needs of exceptional public interest.
Law Nº. 8,958	12/20/1994	Support Foundations Law	Provides for relations between IFES and support foundations.
Law Nº 10,973	12/02/2004	Innovation Law	Provides for incentives for innovation and scientific and technological research in the productive environment.
Law Nº 12,462	08/04/2011	RDC Law	Establishes the Differentiated Public Procurement Regime (RDC).
Law Nº 12,722	10/03/2012	Amendment to the RDC Law	Amends Law No. 12,462, which establishes the RDC.
Constitutional Amendment Nº. 85	02/26/2015	CT&I Constitutional Amendment	Amends and adds provisions to the Federal Constitution to update the treatment of science, technology, and innovation activities.
Law Nº 13,243	01/11/2016	Legal Framework for CT&I	Provides for incentives for scientific development, research, scientific and

			technological training, and innovation.
Law Nº 13,445	05/24/2017	Migration Law	Provides for the rights and duties of migrants and visitors, regulates their entry and stay in the country, and establishes principles and guidelines for public policies for emigrants.
Law Nº. 9,283	02/07/2018	Regulation of the Legal Framework for Science, Technology, and Innovation	Regulates Law No. 10,973, Law No. 13,243, and provisions of Laws No. 8,666 and No. 12,462.
Law Nº. 14,133	04/01/2021	New Public Procurement Law	Law on Public Procurement and Administrative Contracts.

Source: Own elaboration.

In order to produce a summary of the laws that established the basis for the reference definition of this new Legal Framework, Constitutional Amendment Nº. 85/2015[10], Law Nº. 13,243/2016[5] and Decree No. 9,283/2018[11] were selected for discussion in this article. The justification for this selection is based on the prerogative that these three changes represented qualitative advances in the sphere of public power, as well as being important for covering the proposed topic [in] its methodological aspects[1,12].

Constitutional Amendment Nº. 85/2015

Initially, it was necessary to approve Constitutional Amendment Nº. 85, of February 26, 2015, which included new provisions in the Federal Constitution of 1988 with the aim of modernizing and strengthening support for scientific research, technological development, and innovation in the country[10]. This change expanded the possibilities for state action in this field, promoting cooperation between the public and private sectors and establishing a more favorable environment for the advancement of science and technology as instruments of national development, in addition to expanding the role of the state in the formulation and implementation of public policies focused on these areas. In this way, innovation came to be explicitly recognized as an essential element of economic and social development, encouraging coordination between the public and private sectors[1,12].

Among the main changes, we highlight the expansion of the participation of public entities and agencies in defining cooperative actions, allowing for greater coordination of projects, partnerships, and programs aimed at disseminating scientific and technological knowledge. In addition, Constitutional Amendment Nº. 85/2015 fostered international collaboration, enabling joint practices and initiatives with foreign organizations to be encouraged, provided they were aligned with national interests[1,10,12].

When examining measures such as this one, it is clear how important it is for the government to dedicate itself to scientific development combined with technological and innovative advances, as well as highlighting the need for an integrated system. The proposal of this Amendment highlights the objectives of making the SUS digital system accessible, moving towards a reduction in bureaucracy with a view to stimulating the use of technologies in the health sector.

These changes have had a significant impact on the national and regional productive system, promoting an environment more conducive to research and innovation. In addition, the feasibility of this new measure directly benefits patients, who now have the autonomy to check the progress of their results, greater possibilities for making appointments, as well as the efficient exchange of information between patients and health professionals.

The encouragement of cooperation between public, private, and international institutions has enabled the implementation of new policies and strategies to accelerate technological development in the country, thus strengthening its competitiveness and capacity for innovation[1], as seen in the comparison of changes in Table 2.

Table 2. Comparative analysis of the changes brought about by Constitutional Amendment Nº 85/2015 in the Legal Framework for Science, Technology and Innovation

Before Constitutional Amendment Nº. 85/2015	**Changes brought about by Constitutional Amendment Nº. 85/2015**
Art. 23: Provide the means of access to culture, education, and science;	**Art. 23 (item V):** "Provide the means of access **to** culture, education, science, **technology, research, and innovation**."
Art. 24 (item IX): "Education, culture, teaching, and sports."	**Art. 24 (item IX):** "Education, culture, teaching, sports, **science, technology, research, development, and innovation**."
Art. 167: There was no § 5.	**Art. 167, § 5:** "The transposition, reallocation, or transfer of resources from one programming category to another may be permitted, within the scope of **science, technology, and innovation** activities, with the objective of enabling the results of projects restricted to these functions, by means of an act of the Executive Branch, without the need for prior legislative authorization provided for in item VI of this article."
Art. 200 (item V): "To promote scientific and technological development in its area of activity."	**Art. 200 (item V):** "Increase scientific and technological development **and innovation** in its area of activity."
Art. 213 (paragraph 2): "University research and extension activities may receive financial support from the Government."	**Art. 213 (paragraph 2):** "Research, extension**, and innovation stimulation and promotion** activities **carried out by universities and professional and technological education institutions** may receive financial support from the Government."
Art. 218: "The State shall promote and encourage scientific development, research, and technological training."	**Art. 218.** The State shall promote and encourage scientific development, research, **[scientific and technological training, and innovation]**.
Art. 218: There were no paragraphs 1 and 3.	**Art. 218:** The State shall promote and encourage scientific development, research, scientific and technological training, and innovation. **§ 1** Basic scientific and technological research shall receive priority treatment from the State, with a view to the public good and the progress of science, technology, and innovation. **§ 3** The State shall support the training of human resources in the areas of science, research, technology, and innovation, including through support for
Art. 218: There was no § 6.	

Art. 218: There was no § 7.	technological extension activities, and shall grant those engaged in such activities special working conditions and resources. **§ 6** In carrying out the activities provided for in the caput, the State shall encourage coordination between public and private entities at various levels of government. **§ 7** The State shall promote and encourage the activities of public science, technology, and innovation institutions abroad, with a view to carrying out the activities provided for in the caput.
Art. 219 (heading): "The domestic market is part of the national heritage and shall be encouraged to enable cultural and socioeconomic development, the well-being of the population, and the technological autonomy of the country, in accordance with the law." There were no additional paragraphs.	**Art. 219 (heading):** The State shall encourage the formation and strengthening of innovation in companies, as well as in other public or private entities, the establishment and maintenance of technology parks and hubs and other environments that promote innovation, the work of independent inventors, and the creation, absorption, dissemination, and transfer of technology."
Art. 219-A: did not exist.	**Art. 219-A:** The Union, the states, the Federal District, and the municipalities may enter into cooperation agreements with public agencies and entities and with private entities, including for the sharing of specialized human resources and installed capacity, for the execution of research, scientific and technological development, and innovation projects, in exchange for financial or non-financial compensation assumed by the beneficiary entity, in accordance with the law.
Art. 219-B: did not exist.	**Art. 219-B:** The National System of Science, Technology, and Innovation (SNCTI) shall be organized on a collaborative basis between public and private entities, with a view to promoting scientific and technological development and innovation. § 1 Federal law shall provide for the general rules of the SNCTI. § 2 The states, the Federal District, and the municipalities shall legislate concurrently on their specific characteristics.

Source: Own elaboration.

Law Nº 13,243/2016

Law Nº. 13,243/2016 promoted configurations for the SUS, favoring its digital transformation[5]. Before its implementation, this system was marked by bureaucratic processes, such as slow service in the user screening process and a lack of secure procedures for referrals and appointment scheduling, which were factors that negatively impacted society's perception of its quality[1,2,5,12].

This legislation provides incentives for scientific development, research, scientific and technological training, and innovation in various social and economic segments of the country[5]. Thus, by regulating and standardizing, a context was changed in which it became possible to adopt a culture

of technological innovation, modernization of the system, and incorporation of contemporary practices to make these services agile, fast, unbureaucratic, and accessible to those for whom they are intended[12].

The process that regulates the law stems from the aforementioned Amendment and demonstrates the advancement and encouragement of innovation in health through the introduction of a system that aims to simplify access by creating an environment conducive to strengthening the development of new technologies, promoting technological training, and directly benefiting the SUS, insofar as this new measure works in an integrated and efficient manner.

Through the establishment of the Legal Framework, improvements in the system were observed: i) digitization and computerization of user service systems; ii) strengthening of procedures for the recognition and protection of patents; iii) promotion of scientific and technological debureaucratization; iv) broader perspectives on the transfer of scientific knowledge and technologies between Scientific, Technological, and Innovation Institutions (ICTs); and v) companies, expanding partnerships, internship opportunities and programs, incubators, among others[12] .

In this sense, the establishment of the Legal Framework for Science, Technology, and Innovation made changes to some aspects of nine laws, which are: the Law on Imports of Goods for Scientific and Technological Research (Law Nº. 8,010/1990)[13], the Import Exemptions Law (Law Nº. 8,032/1990)[14], the Temporary Hiring Law (Law No. 8,745/1993)[15], the Support Foundations Law (Law Nº. 8,958/1994)[16], the Innovation Law (Law Nº. 10,973/2004)[17], the Differentiated Public Procurement Regime (Law Nº. 12,462/2011)[18], the Federal Teaching Profession Law (Law No. 12,772/2012)[19], the Migration Law (Law No. 13,445/2017[20] and the Bidding Law (Law Nº. 14,133/2021)[21], to create a more favorable environment for research, development, and innovation in institutions, whether public or private[1,5,12].

These changes have impacted regulatory and institutional dynamics, strengthening the open innovation environment and contributing to digital transformation within the SUS, resulting in several modifications (Table 3).

Table 3. Impacts of Law nº 13,243/2016 on the main changes in related legislation

Law Nº. 8,010/1990	
Change implemented	**Amended provision**
Inclusion of ICTs, scientists, researchers, and other qualified agents as beneficiaries of import tax exemptions, IPI, and Merchant Marine surcharges on the acquisition of machinery, equipment, and supplies for scientific and technological research.	Art. 1, §2
Law Nº. 8,032/1990	
Amendment implemented	**Amended Provision**
Details the exemption or reduction of Import Tax for goods intended for research, development, and innovation; expands the list of beneficiaries, explicitly including ICTs as agents eligible for the exemption; and provides for priority and simplified treatment for imports of equipment and inputs used in RD&I projects.	Art. 1

Modifies item I, with the inclusion of subitems "e" and "g": Subparagraph "e": Establishes that imports made by ICTs, as defined in Law No. 10,973/2004, will be exempt from or receive a reduction in Import Tax. Subparagraph "g": Provides for exemption for imports made by companies in the execution of research, development, and innovation projects, subject to criteria and limits to be established by regulation.	Art. 2, subparagraphs "e" and "g" of item I
Law Nº. 8,745/1993	
Amendment implemented	**Amended provision**
Inclusion of item VIII, which expands the possibilities for temporary hiring, authorizing the admission, for a fixed term, of: – Researchers; – Technicians with intermediate-level training in technology; – Technologists; whether Brazilian or foreign nationals, to work on research, development, and innovation projects at institutions dedicated to such activities.	Art. 2, item VII
Law Nº. 8,958/1994	
Amendment implemented	**Amended Provision**
Allows technology parks and hubs, incubators, associations, and companies with public ICT participation to use affiliated support foundations or enter into agreements for this purpose.	Art. 1, §6
Authorizes contractors to directly transfer resources and rights arising from innovation projects to support foundations.	Art. 1, §7
Allows the Technological Innovation Center (NIT) to be constituted as a support foundation, adopting its own legal personality.	Art. 1, §8
Adjusts the provisions relating to the execution of agreements, contracts, and transfers of funds, integrating the new rules for the use of support foundations in innovation projects.	Art. 3
Makes operational and contractual adjustments for the execution of agreements and contracts involving support foundations, in accordance with the new legal framework for science, technology, and innovation.	Art. 4
Law Nº. 10,973/2004	
Amendment implemented	**Amended Provision**
Change in the scope from “industrial development” to "development of the national and regional productive system" of the country.	Art. 1, item I
Expansion of the concept of socioeconomic development to a vision beyond just the industrial sector, also focusing on other strategic perspectives for the country.	Art. 2, item II
Formulated “guiding principles,” generating development of productive systems, where previously there were fewer assumptions driving technological innovation actions.	Art. 3, items I to VII
Contextualization of the reality experienced by the segment in which it can be applied, with a greater focus on issues of organizational identities, institutional challenges, and the relevance of agents in this process.	Art. 4, § 2
Expansion of competencies and responsibilities with regard to projects, programs, and initiatives related to research and innovation in science and technology, with incentives for partnerships between agencies and companies, incubators, development agencies, etc.	Art. 5, items I to IX
Possibility for ICTs to expand and share scientific and technological knowledge with similar agencies, with a view to transferring resources.	Art. 6, § 1

Authorization for agencies in the sector to participate in projects and programs related to innovation and S&T.	Art. 7, item I
ICTs are authorized to transfer exclusive technologies to other institutions.	Art. 8, § 3
Law Nº. 12,772/2012	
Amendment implemented	**Amended provision**
Allows professors, including those working full-time, to hold the position of chief executive of a support foundation (as provided for in Law No. 8,958/1994), provided that they are not appointed to a commissioned position or position of trust, upon decision by the IFE's Superior Council.	Art. 20
Authorizes foundations supporting Higher Education Institutions and ICTs to remunerate their chief executive, whether non-statutory (with an employment relationship) or statutory, provided that the remuneration does not exceed 70% of the limit established for federal Executive Branch employees.	Art. 20-A
Includes the possibility that full-time professors may receive, as part of their work regime, teaching, research, extension, or innovation incentive grants, paid by an official development agency or by a support foundation duly accredited by IFE or by an international organization. Adjusts the limit of dedication to collaborative activities in teaching, research, extension, or innovation projects, allowing up to 8 hours per week (or 416 hours per year), replacing the previous limit of 120 hours per year.	Art. 21
Law Nº. 13,445/2017	
Amendment implemented	**Amended Provision**
Authorizes the granting of temporary visas to foreigners who come to Brazil as scientists, researchers, professors, technicians, or scholarship recipients linked to research, development, and innovation projects.	Art. 14, item V

Source: Own elaboration, based on the analyzed legislation [1,12,13,14,15,16,17,18,19,20,21] .

With regard to Law Nº. 8,010/1990, the changes proposed by the Legal Framework substantially reflected on imports made by the National Council for Scientific and Technological Development (CNPq), by scientists, researchers, and scientific, technological, and innovation institutions active in the promotion, coordination, or execution of scientific and technological research, innovation, or teaching programs and duly accredited by the CNPq[13]. Previously, the innovation aspect was not included[1].

Law Nº. 8,032/1990 amended the provisions on import tax exemptions and reductions, which are also limited to organizations and companies operating in the field of scientific, technological, and innovation development (i.e., the execution of research, development, and innovation projects, the criteria and qualifications for which shall be established by the government in the form of regulations)[1.14].

Law Nº. 8,745/1993 was amended to consider the temporary need of exceptional public interest, among other situations, the admission of researchers, technicians with intermediate-level training in technology, or technologists, whether Brazilian or foreign, for fixed-term research

projects at institutions dedicated to research, development, and innovation[15]. Previously, the text only allowed researchers, whether Brazilian or foreign, to be hired for fixed-term research projects at institutions dedicated to research[1].

With regard to Law Nº. 8,958/1994, Law Nº. 13,243/2016 innovated in the sense that it broadened the scope of action of scientific and technological support foundations in order to support initiatives and projects in teaching, research, and extension and to stimulate innovation[5,16]. In this sense, technology parks and hubs are better structured to propose these changes[1,13].

Also in Law Nº. 8,958/1994, the clause in Article 26 was amended, defining issues related to scholarship exemptions, which do not constitute, for evidentiary purposes, an employment relationship between the scholarship recipient and the granting institution, provided that the purpose of the objective is proven to be related to research, extension, and scientific, technological, and innovation monitoring projects and programs[16]. For the scholarship grantor, the amendment facilitates the binding process, including discrediting it in the context of social security values[1].

In Law No. 10,973/2004 (Innovation Law), the reforms introduced by the Legal Framework redefined its strategic scope. The term "industrial development" was replaced by "development of the national and regional productive system," broadening the focus to sectors beyond industry, such as services and agriculture. Previously, the legislation was restricted to a less comprehensive sectoral view[1,10]. The concept of socioeconomic development was also added, incorporating dimensions such as sustainability and inclusion, while Article 3, with its items I to VII, established guiding principles for innovation, such as the integration of production chains and the stimulation of competitiveness—previously, the Law lacked clear guidelines for these actions.

Similarly, Law No. 10,973/2004[17], the scope of competencies for research projects was contextualized and expanded, encouraging partnerships between public agencies, companies, and development agencies, which facilitated the sharing and transfer of exclusive technologies between ICTs, something that was previously limited by legal barriers[12,17]. Finally, it authorized the shareholding of public agencies in innovation projects, encouraging investments that previously faced legal resistance.

Law No. 12,462/2011 introduced changes to item X of Article 1, which highlights: the use of a differentiated public contract regime (RDC) necessary for carrying out actions in agencies and entities that develop practices related to science, technology, and innovation[18]. With the New Bidding Law (Law No. 14,133)[21], in force since 2021, discussed below, which revoked regimes and other bidding modalities, the text of the RDC of this regulation was deleted[18,19].

Although Law No. 12,772/2012 was partially amended by Law No. 13,243/2016, the changes focused on adjustments to the occupation of positions in support foundations and the remuneration of the directors of these institutions. However, these amendments did not represent a significant structural change in the positions and functions of managers within Federal Educational Institutions (IFE)[19] .

Law No. 13,243/2016, by establishing the Legal Framework for Science, Technology, and Innovation, promoted significant adjustments to the Innovation Law (Law No. 10,973/2004), with direct repercussions on the modernization of public policies, including the Unified Health System[5]. First, the concept of ‘industrial development’ was replaced by ‘development of the national and regional productive system’. This change aims to integrate innovation strategies in all productive sectors (such as agriculture, services, and technology), going beyond the traditional focus on

industry[13]. In the context of the SUS, this facilitates the incorporation of technological solutions in different spheres of public health, from management to direct user care.

Additionally, the formulation of guiding principles, expressed in Article 3, items I to VII, now guides production systems with more defined guidelines for the implementation of research and innovation projects and programs. This normative reorientation is complemented by the contextualization of the reality experienced by the applicable segments, according to Article 4, § 2, which emphasizes the consideration of organizational identities, institutional challenges, and the relevance of the various agents involved, allowing the norms to adapt to the specificities of each context[5].

Finally, the changes promoted by the provisions of Article 5, items I to IX, expand the competencies and responsibilities related to projects, programs, and initiatives linked to research and innovation in science and technology, encouraging the formation of partnerships between public agencies, companies, incubators, and development agencies[5]. This scenario is strengthened by the possibility for scientific, technological, and innovation institutions to share knowledge and transfer technologies (Article 6, § 1), as well as by the authorization for agencies in the sector to take equity stakes in innovation projects and programs (Article 7, item I) and transfer exclusive technologies with other institutions (Article 8, § 3)[5].

With regard to bidding aspects, previously provided for in Law Nº. 8,666/1993 – later revoked by Law Nº. 14,133/2021 –, the benefits of these administrative procedures began to be used as parameters for selecting suppliers and as tiebreaker criteria in processes involving companies that develop scientific, technological, and innovation projects[21]. This approach reinforces the importance of these mechanisms as a foundation for the country's economic development and for the activities of public administration bodies, among which the SUS stands out[13].

Considering that Law Nº. 14,133/2021 establishes that public works, services, purchases, disposals, concessions, permits, and leases must be preceded by a bidding process, which also applies to ICTs and partnerships with the State, the Legal Framework reinforced this understanding. however, it introduced changes to establish an exemption from this procedure for products or services intended for scientific, technological, and innovation development[5,21].

Decree Nº. 9,283/2018

Decree No. 9,283/2018 acts as a regulatory instrument for Law No. 13,243/2016, giving practical applicability to the Legal Framework for Science, Technology, and Innovation. Its legal importance is linked to the operationalization of legal provisions that were previously broad in nature, ensuring the effectiveness of the mechanisms necessary to bring scientific research closer to the productive sector[1,13].

Among the rules established in the Decree, those that simplify administrative procedures for collaborations between ICTs and the private sector stand out, following the provisions of Article 4 of Law No. 13,243/2016 and explaining the specific conditions for formalizing technology transfer agreements, excluding the requirement for bidding in certain scenarios and establishing rules for the division of results from intellectual property[1,11].

One of the central pillars of the Decree was the regulation of Article 5 of Law No. 13,243/2016, which provides for the participation of ICTs in business companies. The normative text defined conditions for the exercise of innovation activities by public servants (Article 14, Decree No.

9,283/2018), allowing them to participate in projects of strategic interest, provided that they are compatible with their original functions and without prejudice to the accumulation of positions[5]. In addition, Article 18 established rules for the remuneration of researchers in cooperative projects, ensuring transparency in the distribution of resources and alignment with institutional policies.

In the financial sphere, the Decree innovated by regulating the autonomy of ICTs in resource management (Article 22, Law No. 13,243/2016), allowing the reallocation of funds between budget items without the need for prior authorization from the control body[5]. This flexibility, provided for in Article 9, sought to streamline the execution of research projects, reducing bureaucratic obstacles historically criticized by the scientific community[1,5]. At the same time, Article 21 of the same law detailed procedures for importing research supplies, simplifying special customs regimes and harmonizing Federal Revenue Service rules with the sector's demands[1].

From a legal standpoint, the Decree introduced unprecedented governance instruments, such as the National System of Information on Science, Technology, and Innovation (Article 25, Decree No. 9,283/2018), which required the integration of public databases for monitoring sectoral policies. This measure, in line with the principle of administrative efficiency (art. 37, 1988 Constitution), reinforced transparency in the application of resources and allowed for the assessment of economic impacts resulting from investments in innovation[1].

In addition, the text advanced in harmonizing national norms with international standards for intellectual property protection, in accordance with World Trade Organization (WTO) guidelines, by establishing criteria for non-exclusive patent licensing (art. 13, Decree No. 9,283/2018). This progress also demonstrates that the enactment of the aforementioned measures was necessary for the Decree to be approved, as well as highlighting the need for investment in technological innovation[1,11].

Despite the advances, there are still some inconsistencies regarding the implementation of provisions that require interinstitutional coordination, such as tax incentive mechanisms for innovative companies (Art. 19, Law No. 13,243/2016), whose effectiveness still depends on complementary regulations by states and municipalities[5]. However, the Decree remained an essential regulatory framework for reducing asymmetries between the legal environment and the dynamic demands of the innovation ecosystem, consolidating the legal certainty necessary for public-private partnerships in strategic sectors[1].

Final Considerations

An analysis of the ST&I Legal Framework reveals its strategic role in the digital restructuring of the SUS, transcending traditional models and incorporating legal mechanisms geared toward modernization. The legislative reforms, consolidated by Constitutional Amendment Nº. 85/2015, Law Nº. 13,243/2016, and Decree Nº. 9,283/2018, established a normative foundation that not only streamlined the interface between research and public services but also dismantled chronic obstacles to the adoption of technologies.

The inclusion of innovation as a constitutional pillar of socioeconomic development, via Constitutional Amendment Nº. 85/2015, expanded the state's commitment to fostering collaborative ecosystems between the public, private, and international sectors. This convergence enabled more flexible public policies, capable of responding to demands for universal and quality healthcare. The 2016 legislation, in turn, operationalized this vision by simplifying technology transfers, encouraging

strategic partnerships, and modernizing essential infrastructure, such as digital service platforms. In addition, the 2018 decree ensured transparency and legal certainty, crucial factors for attracting investment and ensuring the sustainability of initiatives.

In practice, these changes were reflected in the optimization of SUS administration, with an emphasis on the rationalization of investments, training of professionals, and democratization of access to technological solutions. Autonomy in budget reallocation, the simplification of customs regimes for research, and the agility in hiring specialists exemplify how the reduction of barriers accelerated the implementation of innovations.

However, challenges remain, such as harmonizing standards across government spheres, providing ongoing training for managers to deal with technological advances, and mitigating inequalities in access to digital benefits, preventing regional disparities from deepening.

The digitization of the SUS, although progressing, requires critical monitoring to ensure that gains in efficiency do not obscure the humanization of care and citizen inclusion. The interconnection of national databases, transparent resource management, and the targeting of research to local needs are indispensable steps toward consolidating a resilient and equitable system.

In this context, ST&I standards represent not only a legal advance but also a blueprint for the future of public health. Their updating and dialogue between social agents will be decisive in ensuring that technological progress transcends the theoretical plane and materializes in concrete improvements in the population's quality of life, reaffirming the SUS as a universal, comprehensive model aligned with the challenges of the 21st century.

Acknowledgments

I thank God for the light that always guides my path; my family, friends, and boyfriend for their support, affection, and encouragement throughout this journey.

To the CTIS CoLaboratory at Fiocruz-Brasília, where I worked until the completion of this article and where the inspiration for this study came from, I express my deep gratitude for being a fertile space for ideas, learning, and innovation.

I am equally grateful to everyone who, in some way, contributed to making this work possible.

References

1. Portela BM, Barbosa CMM, Muraro LG, Dubeux R. Marco legal de ciência, tecnologia e inovação no Brasil. 2ª ed. Brasília: Juspodivm; 2021.

2. Abdala V. Consumo de serviços de saúde avança 10,3% após pandemia. Agência Brasil [Internet]. 5 abr. 2024 [cited jan. 5, 2025]; Health. Available from: https://agenciabrasil.ebc.com.br/saude/noticia/2024-04/consumo-de-servicos-de-saude-avanca-103

3. De Paula P. 71% dos brasileiros têm os serviços públicos de saúde como referência. Biblioteca Virtual em Saúde [Internet] [cited jan. 5, 2025]; Available from: https://bvsms.saude.gov.br/71-dos-brasileiros-tem-os-servicos-publicos-de-saude-como-referencia/

4. Medeiros AS. Inovação em saúde: avaliação das iniciativas vencedoras do Prêmio de Incentivo em Ciência, Tecnologia e Inovação para o SUS [Dissertação na internet]; Santa Maria (RS): Programa de Pós-Graduação em Gestão de Organizações Públicas, Universidade Federal de Santa Maria; 2020 [cited jan. 5, 2025]. Available from: http://repositorio.ufsm.br/handle/1/22701

5. Brasil. Lei nº 13.243, de 11 de janeiro de 2016. Dispõe sobre estímulos ao desenvolvimento científico, à pesquisa, à capacitação científica e tecnológica e à inovação e altera a Lei nº 10.973, de 2 de dezembro de 2004, a Lei nº 6.815, de 19 de agosto de 1980, a Lei nº 8.666, de 21 de junho de 1993, a Lei nº 12.462, de 4 de agosto de 2011, a Lei nº 8.745, de 9 de dezembro de 1993, a Lei nº 8.958, de 20 de dezembro de 1994, a Lei nº 8.010, de 29 de março de 1990, a Lei nº 8.032, de 12 de abril de 1990, e a Lei nº 12.772, de 28 de dezembro de 2012, nos termos da Emenda Constitucional nº 85, de 26 de fevereiro de 2015 [Internet]. Brasília: Diário Oficial da União, 12 jan. 2016 [cited jan. 10, 2025]. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2016/Lei/L13243.htm

6. Lima FR. Mudanças na gestão pública de saúde: os reflexos das inovações no SUS. São Paulo: Saúde & Progresso; 2022.

7. Cechinel A, Fontana SAP, Della KGP, Pereira AS, do Prado SS. Estudo/Análise Documental: uma revisão teórica e metodológica. Criar Educação [Internet]; 2016 [cited jan. 10, 2025]. Available from: https://doi.org/10.18616/ce.v5i1.2446

8. Cellard A. A análise documental. In: Poupart J, Deslauriers J-P, Groulx L-H, Laperrière A, Mayer R, Pires A P, orgs. A pesquisa qualitativa: enfoques epistemológicos e metodológicos. Petrópolis, RJ: Vozes; 2008.p. 295-316.

9. Creswell JW. Projeto de pesquisa: métodos qualitativo, quantitativo e misto. Porto Alegre, RS: Artmed, 2007.

10. Brasil. Emenda Constitucional nº 85, de 26 de fevereiro de 2015. Altera e adiciona dispositivos na Constituição Federal para atualizar o tratamento das atividades de ciência, tecnologia e inovação [Internet]. Brasília, 27 fev. 2015 [cited jan. 10, 2025]. Available from: https://www.planalto.gov.br/ccivil_03/constituicao/emendas/emc/emc85.htm

11. Brasil. Decreto nº 9.283, de 2018. Regulamenta a Lei nº 10.973, de 2 de dezembro de 2004, a Lei nº 13.243, de 11 de janeiro de 2016, o art. 24, § 3º, e o art. 32, § 7º, da Lei nº 8.666, de 21 de junho de 1993, o art. 1º da Lei nº 8.010, de 29 de março de 1990, e o art. 2º, caput, inciso I, alínea "g", da Lei nº 8.032, de 12 de abril de 1990, e altera o Decreto nº 6.759, de 5 de fevereiro de 2009, para estabelecer medidas de incentivo à inovação e à pesquisa científica e tecnológica no ambiente produtivo, com vistas à capacitação tecnológica, ao alcance da autonomia tecnológica e ao desenvolvimento do sistema produtivo nacional e regional [Internet]. Brasília: Presidência da República; 2018 [cited jan. 10, 2025]. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2018/Decreto/D9283.htm

12. Guimarães R, Morel CM, Aragão É, Paranhos J, Palácios M, Goldbaum M, et al. Política de Ciência, Tecnologia e Inovação em Saúde (CT&I/S): uma atualização para debate. Ciênc saúde coletiva [Internet]. 2021 [cited jan. 10, 2025]. 26(12):6105–6116. Available from: https://doi.org/10.1590/1413-812320212612.18632021

13. Brasil. Lei nº 8.010, de 1990. Dispõe sobre importações de bens destinados à pesquisa científica e tecnológica, e dá outras providências. Diário Oficial da União; 1990. Available from: http://www.planalto.gov.br/ccivil_03/leis/1989_1994/l8010.htm

14. Brasil. Lei nº 8.032, de 1990. Dispõe sobre a isenção ou redução de impostos de importação, e dá outras providências. Diário Oficial da União; 1990. Available from: https://www.planalto.gov.br/ccivil_03/leis/l8032.htm

15. Brasil. Lei nº 8.745, de 1993. Dispõe sobre a contratação por tempo determinado para atender a necessidade temporária de excepcional interesse público, nos termos do inciso IX do art. 37 da Constituição Federal, e dá outras providências. Diário Oficial da União; 1993. Available from: https://www.planalto.gov.br/ccivil_03/leis/l8745cons.htm

16. Brasil. Lei nº 8.958, de 1994. Dispõe sobre as relações entre as instituições federais de ensino superior e de pesquisa científica e tecnológica e as fundações de apoio e dá outras providências. Diário Oficial da União; 1994. Available from: https://www.planalto.gov.br/ccivil_03/leis/l8958.htm

17. Brasil. Lei nº 10.973, de 2004. Dispõe sobre incentivos à inovação e à pesquisa científica e tecnológica no ambiente produtivo e dá outras providências. Diário Oficial da União; 2004. Available from: https://www.planalto.gov.br/ccivil_03/_ato2004-2006/2004/lei/l10.973.htm

18. Brasil. Lei nº 12.462, de 2011. Institui o Regime Diferenciado de Contratações Públicas - RDC; altera a Lei nº 10.683, de 28 de maio de 2003, que dispõe sobre a organização da Presidência da República e dos Ministérios, a legislação da Agência Nacional de Aviação Civil (Anac) e a legislação da Empresa Brasileira de Infraestrutura Aeroportuária (Infraero) (...). Diário Oficial da União; 2011. Available from: https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12462.htm

19. Brasil. Lei nº 12.772, de 2012. Dispõe sobre a estruturação do Plano de Carreiras e Cargos de Magistério Federal; sobre a Carreira do Magistério Superior, de que trata a Lei nº 7.596, de 10 de abril de 1987 (...). Diário Oficial da União; 2012. Available from: https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2012/lei/l12772.htm

20. Brasil. Lei nº 13.445, de 25 de maio de 2017. Institui a Lei de Migração [Internet]. Brasília: Presidência da República; 2017. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2017/lei/L13445.htm

21.Brasil. Lei nº 14.133, de 2021. Lei de Licitações e Contratos Administrativos. Diário Oficial da União; 2021. Available from: https://www.planalto.gov.br/ccivil_03/_ato2019-2022/2021/lei/l14133.htm

Editorial Information

History
Received: April 24, 2025
Revised: October 23, 2025
Accepted: October 31, 2025

Review Process
Doubled-blind peer review.

Open Peer Review
The options for opening the peer review process, including the publication of reviewers' reports, disclosure of identities and interaction between authors and reviewers, were not made available for this article.

Preprint
The manuscript is not a preprint.

Similarity Check
This article was submitted to textual similarity checking using the CopySpider software.

Authors' Contributions
M.H. Ribeiro: conception/design of the article, data analysis and interpretation, and manuscript drafting.
J.R.C. Costa: critical review of the content and approval of the final version of the article.

Conflict of Interests
The authors declared that there is no conflict of interest of a personal, commercial, academic, political, or financial nature related to this article.

Funding
Not applicable.

Ethical Approval of the Research
Not applicable.

Availability of Research Data
Not applicable.

Declaration of Use of Artificial Intelligence (AI) Tools
Not applicable.

Publisher
Fundação Oswaldo Cruz (Fiocruz), Health Law Program, Brasília, DF, Brazil.

How to cite (Vancouver)
Ribeiro MH, Costa JRC. The Legal Framework for Science, Technology and Innovation and its role in the digital transformation of the Unified Health System. Cad. Ibero-Am. Direito Sanit. 2026;15:e2026002. doi: 10.17566/ciads.e2026002