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Competency gaps and institutional challenges for translational research in medical devices: insights from Brazilian researchers

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Abstract

Background The translational research approach aims to accelerate the innovation process. In the healthcare sector, this process is highly regulated and requires a broad set of skills. This study with researchers from Brazilian institutions aimed to identify the knowledge, skills, and structures that permeate the process of translating research into medical devices and to what extent they are present in Brazilian research groups working in the area.

Methods A structured questionnaire was applied in which the characteristics of the participants and the level of mastery in each skill were analyzed. Fisher's exact test was performed to verify the association between the percentages of knowledge and importance. Pearson's Chi-square test was also performed to verify the association between the sum of knowledge, categorized by the median, and the characteristics of the questionnaire participants. Finally, an exploratory factor analysis (EFA) was performed to validate the questionnaire construct.

Results One hundred two researchers working in the area of health innovation in Brazil, especially in the medical devices segment, answered the questionnaire. These researchers come from different regions of the country and work in several areas of knowledge, such as engineers (28%), doctors (12%), information technology and connectivity professionals (11%), pharmacists (8%), nurses (7%), and other formations (34%). The research revealed that a small number of these researchers have a good level of knowledge in human factors engineering and usability (23%), in patent legislation and asset management (24%), in pre-clinical and clinical trials (29%), in business plans (30%) and in the requirements of the technology incorporation process in the SUS (31%). The results reveal significant learning gaps and institutional deficiencies in essential skills and structures for translational medical device research.

Conclusion Understanding the necessary skills and gaps to be filled can contribute to the adoption of institutional strategies and the formulation of public policies capable of promoting more effective results for the Brazilian health system.

Keywords Translational research, Health innovation, Medical devices, Competencies

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Introduction

The current debate surrounding technological innovation in healthcare, which encompasses developing new products or processes for application in health systems, poses significant challenges for academia. These challenges are particularly evident in developing competencies that facilitate the transfer of scientific knowledge to the productive sector and society [1–8].

Brazil occupies the 49 th position in the ranking that measures the performance of the innovation ecosystems of 132 economies (Global Innovation Index). This ranking is inferior to other low-income countries, such as Thailand (43rd), Turkey (39 th) and Bulgaria (35 th), Malaysia (36 th) and China (12 th) [9]. A study indicates that, while Brazil remains in 14 th place in the ranking of 51 countries with the highest scientific output globally, the country experienced a 7.4% decrease in scientific article publications in 2022 compared to 2021 [10]. This decline was not observed in other emerging nations, such as India and China. Brazil's underperformance is also reflected in the long, bureaucratic, costly process of developing innovative health technology [11].

The literature highlights that innovation performance is also directly linked to learning, which is based both on formal education processes (science) and on empirical and tacit knowledge, grounded in learning by doing, using, and interacting [3, 12, 13]. These continuous training processes involve economic structures, organizational frameworks, and professional relationships, where both formal and implicit knowledge are leveraged to foster interactive learning [7, 14–16].

The Translational Research (TR) approach aims to accelerate the innovation process, from the transposition of basic and applied science to the provision of new products or processes to society [17–23]. In this approach, the weaving of knowledge and the progress in the different stages of research is achieved through multidirectional flows and multidisciplinary, transdisciplinary dialog and technical-scientific cooperation between the various actors involved in a systemic inter-institutional and intersectoral way [15, 24–26].

This translation process is strongly regulated in the health sector and incorporates the final stages of development, relating to clinical research, health regulation, production, and the incorporation of technologies into the healthcare system [27–32]. The existing literature indicates that these stages presuppose learning a set of technical, ethical, intellectual property, and health standards requirements. In addition, it requires mastering the parameters adopted for incorporating the technology into the healthcare system and conditions relating to the financing and payment model [33].

Boterf [34] considers that the development of these competencies findings from the multidimensional combination of available resources, knowledge, skills, and attitudes, alongside the ability to produce effective responses. Moreover, studies highlight that within this set of competencies, in addition to hard skills (specific technical skills), soft skills (personal and behavioral abilities) such as motivation, teamwork, ethics, planning, effective communication, and cultural awareness are increasingly valued for academic and professional success [35–37]. Consequently, they are essential for the economic development of a country and the creation of sustainable and resilient healthcare systems.

According to Illeris [14], the learning process-which involves content (knowledge and skills), incentive (motivation), and interaction (communication and cooperation)-is the area of tension that fosters the development of competencies, which is related to the ability to address different challenges imposed in professional matters and throughout life. In this perspective, the stages and requirements of the research translation process require the development of individual competencies by researchers and institutional capacities by university support teams, e.g., encouragement, communication, organizational structure, process, and management. Owing to the locoregional specificities outlined by Lundvall [3], it is critical to understand how those competencies are developed in articulation with the innovation system, the production system, and the local demands of the healthcare system. In Brazil, the body of literature on the Health Economic-Industrial Complex (HEIC) explains the conformation of the productive bases and the interdependence between health services and the industrial and innovation segments [38, 39]. This conception highlights health as a critical economic sector that combines economic and social development based on the convergence of efforts to generate well-being and health.

In this conception, translational research can be viewed as an approach within the broader context of the National Innovation System (NIS) and the Health Economic-Industrial Complex (HEIC) as it is favorably impacted by improved interaction among local players (university, health services, government, and industry) [30, 40, 41]. Concurrently, it may help delimit translational research to a specific industrial segment, as this study proposes. This could favor understanding the institutional arrangements that support the development of competencies, content, incentives, and interaction and thus shape the innovation process in a particular way.

Among other features, the medical device industry is directly linked with local production, access, and safe use [42, 43]. The World Health Organization (WHO) underscores that local production is essential to mitigate

inequalities in access to medical devices. Medical technologies designed and developed in high-income countries often falter in low- and middle-income countries due to structural challenges and local contexts [44–46]. The medical devices segment encompasses technologies indispensable in health services and healthcare. In 2007, with Resolution WHA60.29, the WHO recognized the importance of these products for universal health coverage and urged member states, including Brazil, to broaden their expertise around such technologies [47, 48]. The WHO has also acknowledged the relevance of these technologies' availability and safe use in achieving the Sustainable Development Goals (SDGs) related to health [47, 49]. In addition, amidst the rapid digital transformation in health in the context of global health, particularly after the COVID- 19 pandemic, it is noteworthy that the WHO expressed its concerns by introducing a set of guidelines for the ethical and effective use of artificial intelligence to enhance diagnosis, treatment and health research for the public benefit of all nations [50].

Within this context, the development of competencies in health-related academic programs is pivotal for driving innovation within health systems. The literature underscores the importance of equipping students and researchers with both technical expertise and essential soft skills-such as teamwork, critical thinking, and adaptability-empowering them to effectively navigate the complexities and dynamic challenges of contemporary health environments [51–53]. In the Brazilian context, a deeper investigation into these competencies can support the design of further targeted strategies and public policies, accelerating the development and implementation of innovative solutions tailored to the specific challenges of the healthcare system.

In response to these challenges, this study engaged Brazilian researchers working in health innovation to elucidate which knowledge, skills, and frameworks are considered relevant for the translation of research into medical devices and to what extent these elements are present in Brazilian research groups operating in this field.

Methods

This is a study with data analysis gathered from the application of a structured questionnaire that sought to understand the competencies and conditions that affect the development of translational research in medical devices in Brazil.

Given the need to map out the main concepts and terms, a systematic review of the literature, of the Scoping Review type, entitled: "Translational research in health technologies: a scoping review" [33]. From the qualitative analysis of the data, this review allowed for the characterization of translational research, the identification of the aspects and attributes that favor and the barriers faced by researchers and academic laboratories linked to Brazilian institutions in the process of translating research. The findings of the review made it possible to identify three dimensions of understanding, which helped to elucidate the most relevant aspects that should be included in the questionnaire. These were: 1) the knowledge dimension, which refers to the content that can be learned; 2) the skills dimension, which indicates an acquired ability; and 3) the dimension relating to institutional capacities and structures, which refers to the conditions of the physical structures or management of an institution or a group of institutions.

With these dimensions and the contents identified in the literature, the questionnaire was formulated and then validated by experts with at least 10 years of experience in research and technology development in the health sector, before being applied.

Target population and sample

To select the research participants and establish the profile for completing the online questionnaire, searches were carried out on November 20, 2022, in the following databases:

a) Health Research [54], a public database maintained by Brazil's Ministry of Health (MoH), which contains research funded by the MoH. For selection on this database, the filters "technological development research" and "translational research" were considered, with no time frame. This database identified 250 researchers coordinating projects;
b) Directory of Research Groups of the National Lattes Platform [55], in which the following search options were used: by name, all words, repercussion in the research group (purpose), and lines of research. The following descriptors were used: "health innovation", "translational health research" and "medical devices" or "health technologies" with no time frame. This directory identified 556 researchers who are members of research groups working in the area;
c) Brazilian Network for Health Technology Assessment (REBRATS), all researchers who are part of any Health Technology Assessment Centers (NATS) were considered for the universe. In this group, 285 researchers were identified. The Brazil Clinical Engineering Group, included due to its relevance to the segment [50], has 277 members; and
d) The patent directory of the Brazilian National Institute of Industrial Property (INPI) [56], which identifies patents granted in Brazil. This database was selected by searching for "exact expression" in the

"abstract" with the filter "medical device". In this directory, 792 patent processes were identified, with a time frame of 2015 - 2022, including 42 inventors resident in Brazil.

After this multiple selection, repetitions were disregarded, such as researchers who appeared in more than one group or platform, totaling the target population of 880 researchers.

The questionnaire used a Likert scale, in which values were assigned from 1 to 5, with zero being assigned to the item "I don't know". The maximum admissible sampling error was 2.5% (0.1 point on the Likert scale adopted), with a 95% confidence level. According to the calculations used to define the sample size (being a simple random sample of the population), it would be necessary to obtain at least 87 valid answers to the questionnaire.

Questionnaire

The survey was evaluated in a workshop with a group of five expert researchers, with technical and scientific production and experience in the development of medical devices and technologies for use in healthcare, similar to those of the target sample. The final version of the questionnaire was validated by expert consensus and included four sections:

i) general identification, such as age, length of experience, state where they work, academic background, degree and area of work (6 questions);
ii) knowledge and competencies necessary for a translational researcher, containing the attribution of importance to the content or technique indicated and the researcher's self-assessment of their mastery of this content or technique (20 likert scale questions and 2 open questions);
iii) skills, referring to the abilities that can be acquired for the development of translational research, containing the attribution by the researcher of the importance of mastering these skills (5 likert scale questions and 2 open questions); and
iv) institutional structure and capacity, referring to the physical or management conditions of an institution or a group of partner institutions, containing the attribution by the researcher of the importance of these conditions for the development of translational research (14 likert scale questions and 2 open questions).

The four sections were also validated using a confirmatory factor analysis. All in all, the sections contained 45 (forty-five) questions, of which 6 (six) were identification questions, 29 (twenty-nine) were Likert scale questions (Not important/Slightly important/Moderate/Important/Very important), 10 (ten) were Likert scale questions (No knowledge/Little knowledge/Fair knowledge/Good knowledge) and 6 (six) were open questions.

The questionnaire in Google Forms format was sent to the e-mail addresses listed on the platforms, to the virtual social networks, and the specifically identified communication groups (Rebrats and Clinical Engineering Brazil Whatsapp groups). The questionnaire, developed specifically for this study, can be found in the Supplementary Material.

Data analysis

A descriptive analysis was carried out of the characteristics of the participants, the knowledge, its importance and the degree of mastery by the researchers, the individual capabilities, as well as the importance of institutional structures that can contribute to the development of translational research into medical devices in Brazil. These data were presented in absolute values or percentages in the form of figures or tables. To check the association between the percentages of knowledge and importance, Fisher's exact test was performed. Pearson's chi-square test was also carried out to verify the association between the sum of knowledge (categorized by the median) and the characteristics of the questionnaire participants. exploratory factor analysis (EFA). The EFA is a robust analysis, with more solid evidence for theoretical construction, a priori, for the confirmation of the established factors, named as Knowledge, Capacity and Structure, and Institutional Capacity. The estimator used was the Weighted Least Squares Mean and Variance-Adjusted (WLSMV). To identify acceptable measures for the model, the Comparative Fit Index (CFI) was used - ideal value above 0.9; Tucker-Lewis Index (TLI) - acceptable above 0.9; Root Mean Square Error of Approximation (RMSEA) - acceptable up to 0.05. All data was analyzed using packages (pandas and numpy) in the Python language, in addition to the R software, using the "lavaan" package for EFA modeling.

The six open questions in the questionnaire were analyzed according to the phases proposed by Bardin [57]: organization of the analysis, coding, categorization, and treatment and interpretation of the results. The content analysis of the open questions explored a qualitative perspective, analyzing both the frequency of occurrence of certain contents, constructions, and references, as well as relevant aspects for establishing categories that contribute to the analysis.

The complete data from the applied questionnaire and the research results are available for public consultation and use in the Zenodo repository. This includes both the questions and the answers collected, offering

valuable insights for researchers and professionals in the field. Access to the dataset in Zenodo is via a direct link (https://doi.org/10.5281/zenodo.10622263).

Ethical approval

The online questionnaire used in this study was anonymized and involved low risk. However, it was approved by the Research Ethics Committee of the Federal University of Rio Grande do Norte, Natal, Brazil, through letter CAAE-No. 65474322.9.0000.5292 and following the Helsinki Accords (as amended in 2004). The terms of acceptance of participation and the participant's rights are set out in the Informed Consent Form (ICF) that was part of the questionnaire presentation under the General Data Protection Law (LGPD) and CNS Resolution 466/12, Resolution 510/2016 and Resolution 580/2018. Consent to participate in this study was obtained implicitly through the survey.

Limitations

A limitation of the study regarding the methodological design is related to the non-standardized understanding of what translational research is by the researchers who answered the questionnaire. To minimize this limitation, the concept of translational research from the theoretical framework adopted was included in the initial Questionnaire section. In addition, a homogenization of the sample was sought, as can be seen in the Target population and sample section in the Methods section.

Results

A total of 102 researchers working in the field of health innovation in Brazil answered the questionnaire, especially in the medical devices segment. The distribution of researchers across Brazil can be seen in Fig. 1.

As shown in Fig. 2, the researchers in the sample mostly concentrate their work on coordinating projects and developing medical devices.

The questionnaire was answered by individuals with a higher level of qualification, the majority of whom hold master's (33%) and doctorate (44%) degrees (see Fig. 3).

The area of knowledge shows multidisciplinarity in the field of innovation, marked by the participation of researchers from the health and engineering/technology fields, as Fig. 4 shows:

The knowledge needed to develop translational research identified in the international literature was compared with the self-perception of Brazilian researchers working in the segment [33]. In general, the researchers confirm the importance of the knowledge found in the literature, but the data analysis shows that they have different levels of knowledge, as shown in Table 1:

Researchers answering the questionnaire presented a better level of knowledge in Technical Standards applicable to the medical device under development (47%) and a lower level of mastery in Design, Human Factors Engineering and Usability (23%). The latter is low even among engineers (33%).

Also noteworthy is the small number of researchers who had a good level of knowledge of patent legislation and asset management (24%), pre-clinical and clinical research (29%), the business plan for the technology

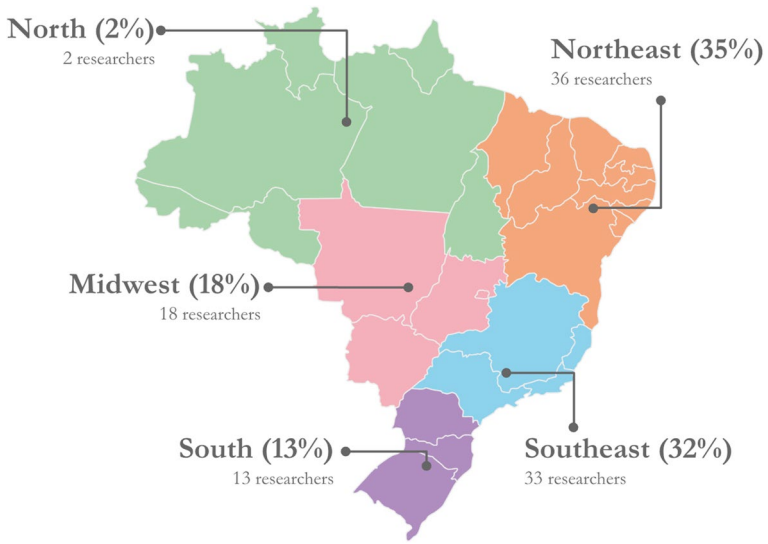

Fig. 1 Sample distribution of researchers across Brazil (n = 102+)

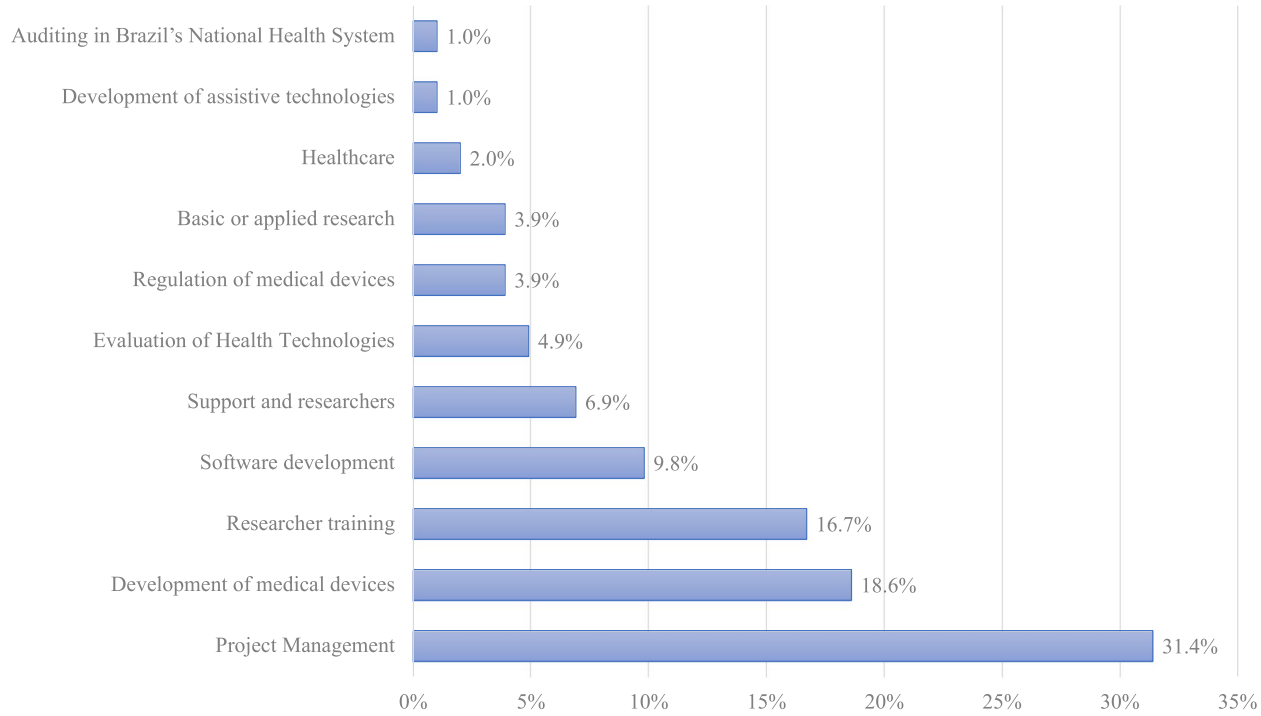

Fig. 2 Field of activity of the researchers (n = 102)

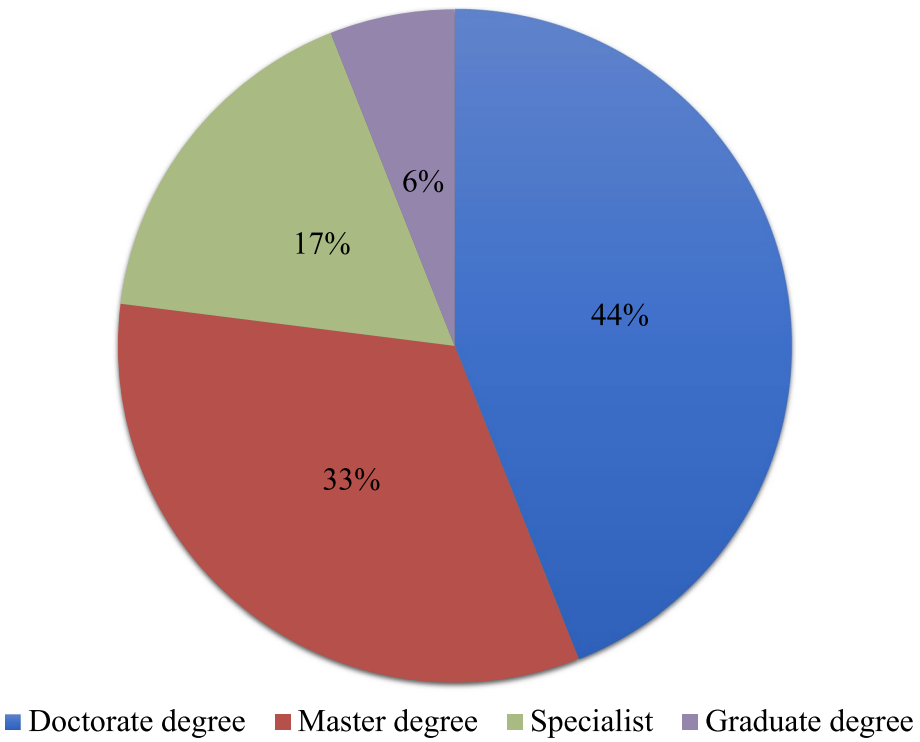

Fig. 3 Qualification of the researchers in the sample (%)

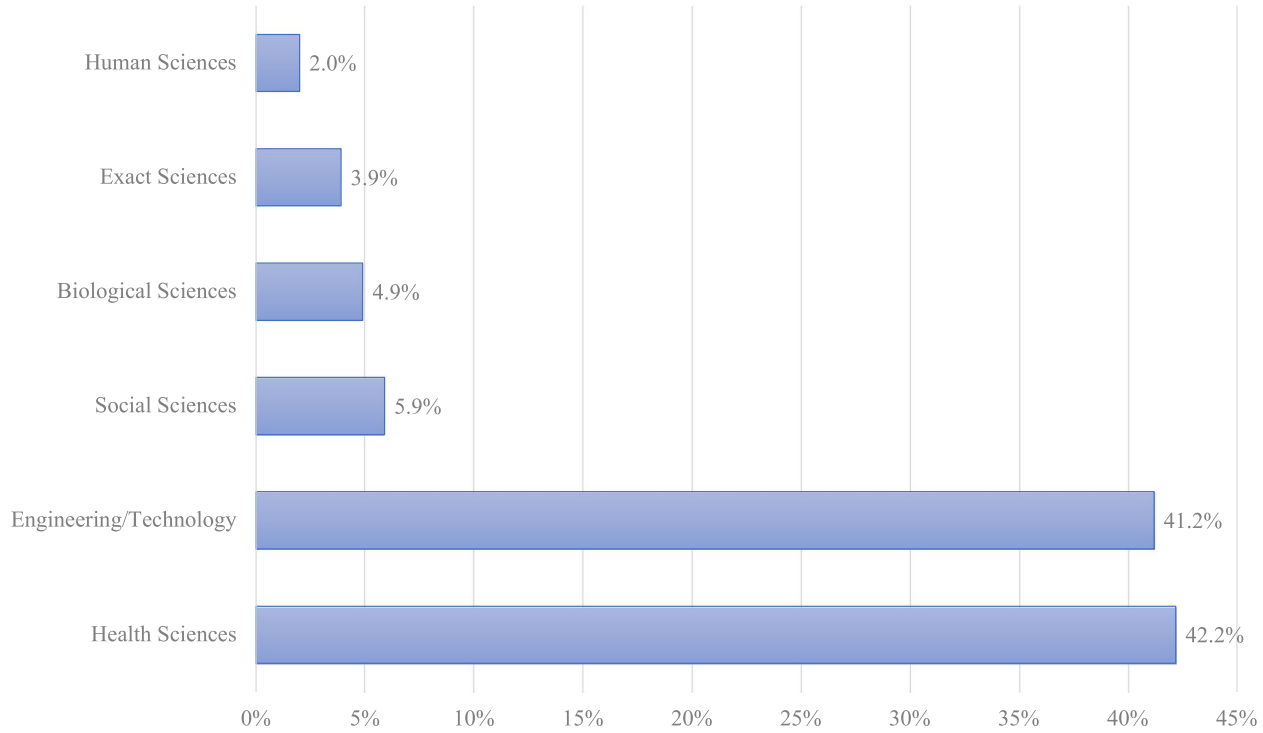

Fig. 4 Area of expertise of the researchers in the sample (%)

Table 1 Researchers' level of knowledge (n = 102)

Dimension	Knowledge		
	Good	Regular	Little
Technical Standards	48	31	23
ANVISA Standards	30	35	37
Ethical Standards and Procedures	39	38	25
Intellectual Property Legislation (INPI)	24	40	38
Clinical Guidelines and Protocols	43	37	22
The process of incorporating technologies into SUS[a]	32	42	28
Technology business plan	30	34	38
Project management tools and methods	38	30	44
Pre-clinical and Clinical Research	29	41	32
Design, human factors engineering and usability	23	38	41

[a] SUS: Brazilian Health System

(30%), and the process of incorporating technologies into the SUS (31%), knowledge considered important by 89%, 95%, 92% and 91% of researchers, respectively.

Among the researchers who coordinate projects (n= 32), only 43% considered they had a good level of knowledge of the technology's business model (demand, production capacity, suppliers, logistics, and supply chain), only 37% were proficient in managing innovation projects using tools and methodologies (translational readiness level — TRL, project and risk management), and only 31% said they had a good knowledge of economic evaluation studies (cost-effectiveness, budgetary impact and payment or reimbursement mechanism). These skills are associated with good practices in managing health innovation projects.

On the other hand, researchers who work directly in the development of equipment, diagnostic tests, orthoses, or prostheses (n= 19) or in the development of embedded software for clinical, diagnostic, or therapeutic purposes, which process medical, managerial, demographic, or epidemiological data (n= 10), consider themselves to have a good level of knowledge of Anvisa standards (only 41%), lines of care, use protocols, clinical protocols, and therapeutic guidelines (only 37%) and mastery of designing and conducting validation tests, safety tests and preclinical and clinical trials (only 31%). This knowledge is pointed out in the literature as essential for moving forward in the translation stages of the research [58–62].

The skills identified were also compared with the perception of their importance for Brazilian researchers working in the sector, with the following being considered critical: identifying unmet clinical or managerial needs (99%), working collaboratively (98%), interacting with patients, managers, and health professionals to assess the technical, patent, clinical and economic

feasibility of the technology (97%) and techniques for horizon monitoring and technology prospecting (95%).

When comparing the proportions between the knowledge and skills needed by translational researchers and their perception of the importance of this knowledge, there was a significant association between the team's knowledge of the process of incorporating technologies into Brazil's SUS (economic evaluation studies, cost-effectiveness, budgetary impact, payment or reimbursement mechanism for the use of the product, organization of the system by level of complexity), i.e., 75.5% of those interviewed who had regular or good knowledge attributed it as an essential item ($p = 0.005$). At the limit of significance, it should be noted that 71.4% of team members consider their knowledge of the design and conduct of validation tests, safety tests, and pre-clinical and clinical trials to be an important item and have regular or good knowledge ($p = 0.088$). The other competencies analyzed had no significant relationship between having the knowledge and its classification as important. The analysis is based on the data described in Table 2.

When comparing the proportions of the level of knowledge on the topics with the demographic and contextual characteristics of the survey participants, there was a significant association with sufficient knowledge among researchers over 60 years of age (76.92%; $p = 0.026$) and coming from the northeast region (82.35%; $p = 0.003$). There was no significant relationship between sufficient knowledge and length of time working in the area, area of training, area of knowledge and current predominant area (Table 3).

Regarding the importance of institutional structure and capacity, referring to the physical or management conditions of an institution or a group of partner institutions, the researchers considered all the capacities listed to be important, as described in Table 4.

Other knowledge and skills that were not included in the questionnaire were suggested by the researchers as being important or indispensable for a translational research team (open questions), as shown in Table 5.

In the analysis of the open questions, the emphasis on transdisciplinary themes is remarkable, such as a favorable environment and agility for innovation, partnerships, entrepreneurship in the public sector, international cooperation, the establishment of the Health Technology Assessment Centers, the team's resilience to setbacks in the innovation process (tolerance and learning from mistakes). In the Management and Communication area, most of the contributions came from team, project and risk management, while in the Financing and Business

Table 2 Importance and level of knowledge of competencies

Competencies	Important	Knowledge		*pValue*
		Little	Regular/Good	
Technical standards for the development of a new medical device or new software for use in healthcare (Inmetro, ABNT, ISO, IEC, LGPD, DataSUS, SBIS, etc.)	**No**	-	-	*
	Yes	23 (22.8%)	78 (77.2%)	
ANVISA rules applicable to the process of research and registration of a medical device or software for use in healthcare (RDC 548/2021, 153/2017, 185/2001, NT 04/2012, 657/2022, etc.)	**No**	1 (100%)	0 (0%)	0.367
	Yes	35 (36.1%)	62 (63.9%)	
Norms and procedures of the ethical regulatory framework (CNS Resolutions, CEP/CONEP System, and Brazil Platform)	**No**	-	-	*
	Yes	25 (24.5%)	77 (75.5%)	
Intellectual property legislation (INPI) and asset management (institutional innovation policy)	**No**	1 (100%)	0 (0%)	0.366
	Yes	36 (36%)	64 (64%)	
Conceptual model of the disease, problem area, workflow or process (Lines of Care, Use Protocols, Clinical Protocols and Therapeutic Guidelines (PCDT), Brazilian Guidelines, Burden of Disease and Guidelines from Medical Societies, etc.)	**No**	1 (100%)	0 (0%)	0.218
	Yes	21 (21%)	79 (79%)	
Process of incorporating technologies into the SUS (economic evaluation studies, cost-effectiveness, budgetary impact, payment or reimbursement mechanism for the use of the product, organization of the system by level of complexity)	**No**	4 (100%)	0 (0%)	0.005
	Yes	24 (24.5%)	74 (75.5%)	
Knowledge of how to draft a technology business plan (demand, production capacity, suppliers, logistics, and supply chain)	**No**	2 (66.7%)	1 (33.3%)	0.294
	Yes	34 (35.1%)	63 (64.9%)	
Knowledge and use by the team of tools and methodologies capable of foreseeing the obstacles of translational research (assessment of the translational readiness level-TRL, project, and risk management)	**No**	2 (100%)	0 (0%)	0.169
	Yes	39 (40.2%)	58 (59.8%)	
Knowledge of how to design and conduct validation tests, safety tests and pre-clinical and clinical trials (where appropriate).	**No**	2 (100%)	0 (0%)	0.088
	Yes	28 (28.6%)	70 (71.4%)	
Knowledge of product design, human factors engineering and usability	**No**	2 (100%)	0 (0%)	0.154
	Yes	38 (38.4%)	61.6%	

Table 3 Level of knowledge by demographic and contextual characteristics

	Insufficient (up to 20)	sufficient (> 20)	*p*Value
Age group			
Over 60 years old	3 (23.08%)	10 (76.92%)	0.026
From 25 to 34 years old	14 (73.68%)	5 (26.32%)	
From 35 years old to 44 years old	24 (61.54%)	15 (38.46%)	
From 45 to 59 years old	19 (65.52%)	10 (34.48%)	
Country Region			
Central-west	10 (55.56%)	8 (44.44%)	0.003
Northeast	28 (82.35%)	6 (17.65%)	
North	3 (100%)	0 (0%)	
Southeast	12 (37.5%)	20 (62.5%)	
South	7 (53.85%)	6 (46.15%)	
Time of experience in the area			
Over 15 years	21 (45.65%)	25 (54.35%)	*
From 10 years to 15 years	14 (63.64%)	8 (36.36%)	
From 3 years to 5 years	10 (76.92%)	3 (23.08%)	
From 5 years to 10 years	10 (71.43%)	4 (28.57%)	
Academic background			
Nursing	4 (66.67%)	2 (33.33%)	*
Engineering	14 (48.28%)	15 (51.72%)	
Pharmacy	4 (57.14%)	3 (42.86%)	
Medicine	6 (50%)	6 (50%)	
Information and Communication Technology	10 (90.91%)	1 (9.09%)	
others	22 (62.86%)	13 (37.14%)	
Major field of knowledge			
Health Sciences	26 (60.47%)	17 (39.53%)	*
Engineering/Technology	25 (60.98%)	16 (39.02%)	
others	9 (56.25%)	7 (43.75%)	
Predominant field of activity			
Project Management	21 (65.62%)	11 (34.38%)	*
Development of medical devices	8 (42.11%)	11 (57.89%)	
Software development	7 (70%)	3 (30%)	
Training researchers	8 (47.06%)	9 (52.94%)	
others	16 (72.73%)	6 (27.27%)	

Model area, in addition to the ability to outline a business plan, the researchers also attributed importance to interaction with companies in order to understand the demands of the sector. Another highlight is the set of skills inherent to the 4.0 technological revolution that permeate the areas of ICT and Research Methodology, such as systems engineering, testing and validation, integration, analysis and data science.

The questionnaire structure was validated using Confirmatory Factor Analysis (CFA). This began with the theoretical construction, a priori, of the three dimensions: Knowledge, Capacity and Institutional Structure. In the CFA modeling to confirm the variables that make up the "Capacity" dimension, question 31 (Effective communication with different actors involved in the research) was removed, as it did not have an acceptable factor load in contributing to the final model.The factor loads presented in the final CFA model in Fig. 5 were sufficient to build a parsimonious theoretical model, confirming the theoretical model with three dimensions, with values of CFI = 0.907, TLI = 0.980 and RMSEA = 0.028. The values indicated show low error (RMSEA) and good fit (CFI and TLI, close to 1). The values for each factor loading of the dimensions and questions are shown in Fig. 6.

Description:

Knl-Knowledge: $v8 + v10 + v12 + v14 + v16 + v18 + v20 + v22 + v24 + v26$

Table 4 Institutional structure and capacity

Description
Continuous formation for the team on regulatory and technical requirements, financing issues, intellectual property and other relevant topics (100%)
Support on existing funding sources for each stage of the research (99%) and administrative, legal and/or regulatory support (99%)
Provision of mentoring by experienced researchers and experts for new researchers (99%)
Engagement of institutional leaders to overcome technical and administrative barriers (99%)
Development of an environment in the institution favorable to entrepreneurship, creation of start-ups and transfer or licensing of technology (99%)
Organization and maintenance of a multidisciplinary team with adequate dedication to research (98%)
Adoption of good laboratory practices (GLP) and project quality management system (98%)
Partnerships for collaborative or network action linking multiple researchers, research centers and government (98%)
Partnership with the industry to develop innovations (98%)
Own or shared physical infrastructure for prototype development under best practice conditions (97%)
Support for researchers in project management, monitoring and evaluation (97%)
Physical infrastructure for pre-clinical and clinical research in-house or in collaboration with another institution (97%)
Own or shared physical infrastructure for developing proof of concept and in vitro tests (96%)

Table 5 Institutional knowledge, skills, structure and capacity identified in the open questions

Area	Freq.	Textual Corpus
Management and Communication	15	"Agility in the innovation ecosystem, with emphasis on management models. A counterproductive factor in the innovation process is a lack of agility."; "Timing is essential and the major challenge is management."; "Resilience to setbacks in the RD&I process"; "Risk management inherent in the development and contract handling and moderation of expectations with stakeholders."; "Continuous interaction and exchange of experience and knowledge with companies in the productive sector."
Financing and Business Model	12	"Understanding the financing methods for innovation projects, whether through incentives, calls for proposals or venture capital."; "Whether a business model is viable or does not depend on a single customer."; "Interaction with health product manufacturers and researchers to identify specific needs."
Public Policies and Institutional Strategies	11	"Direct financial incentive for researchers who attract large projects and resources, encouraging the pursuit of new projects and opportunities."; "Implementation of Health Technology Assessment Centers (NATS)."; "The regulation of innovation initiatives and partnerships, not only between the public and private sectors but also by re-evaluating internal production relations, ensuring that government employees have the right to undertake."; "Strengthening international cooperation strategies to promote the development of skills at the frontier of knowledge."
Team	9	"Team with permanent involvement of users (doctors/patients) in researching demands for improvements or new devices."; "Ability to work in multidisciplinary groups."; "Experiences with managers, professionals and users of the health system with similar technologies"
Information and Connectivity Technologies (ICTs)	8	"Data science techniques in healthcare."; "Data integration."; "Systems engineering, product testing, and validation."
Technical and Sanitary Regulation	8	"Testing, calibration, certification, validation."; "Knowledge of the incorporation process into the ANS catalog in addition to CONITEC."; "Monitoring the world regulatory framework."; "Interaction with health product manufacturers and researchers to identify the requirements of the specific application from a technical, metrological and scientific point of view."
Research Methodology	8	"Regarding the scientific method, implementation science and its tools and techniques; some kind of literature review method, to understand the state of the art with scientific and gray literature."; "Data Science and Analysis."; "Capability of interpreting metrological results, instrumentation, and biomedical equipment."
Education and Training	6	"The multidisciplinary team needs to understand the business (research, development, application). Understanding what it is all about and then applying the knowledge is important."; "Creativity for product generation."; "Continuing education."; "Capability to quickly show the customer a minimum viable product (PITCH)."

Cpt-Capacity: $v30 + v32 + v33 + v34$

Str-Structure: $v37 + v38 + v39 + v40 + v41 + v42 + v43 + v44 + v45 + v46 + v47 + v48 + v49 + v50$

Discussion

Until it is available for use, a medical device goes through several stages of research and development which differ

(a) Knowledge (b) Skills

(c) Institutional structure and capacity

Fig. 5 Wordclouds of open questions

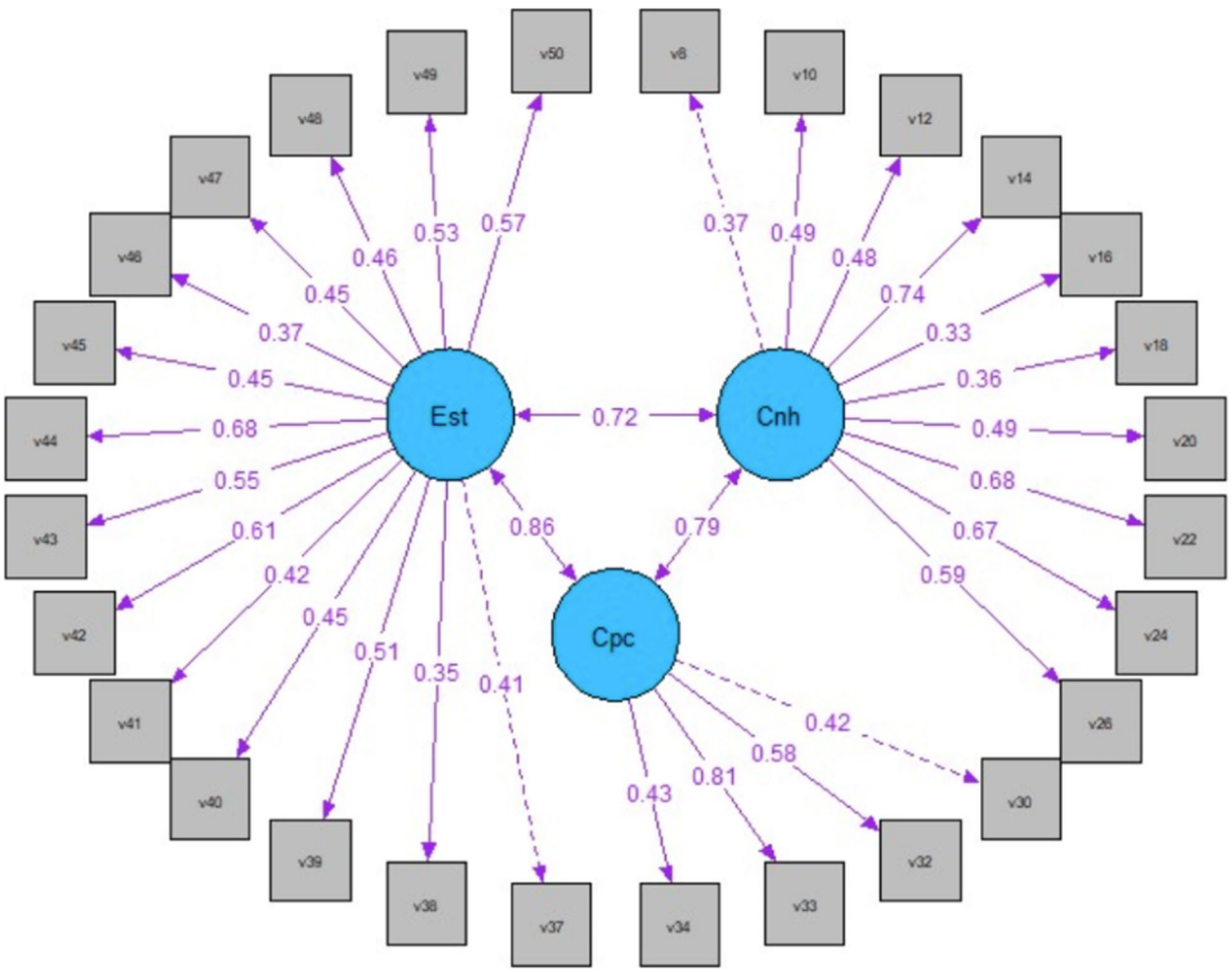

Fig. 6 Correlation diagram of the Confirmatory Factor Analysis factors

greatly depending on the type of technology and the rules of the regulatory process to which the product is subject [58, 63–65]. Analysis of the data obtained from Brazilian researchers confirms this systemic and multidisciplinary nature, which involves the mastery of various skills in the process of developing translational research into medical devices [8, 59, 66–69].

The data obtained also shows important gaps in knowledge considered essential for the development of a medical device, since the researchers participating in this research considered the following domains to be regular or low:

1) patent and sanitary regulation;
2) technology business plan;
3) on the design and conduct of validation tests;
4) safety and pre-clinical and clinical trials; and
5) knowledge of economic evaluation, such as cost-effectiveness, budgetary impact, payment or reimbursement mechanisms.

The latter are fundamental to the process of incorporating technology into Brazilian Health System (SUS) [70–74].

The findings on the low regulatory domain in clinical trials corroborate Nascimento's study [58], which points out that the regulatory environment for the clinical evaluation of medical devices involves various issues related to the level of transparency and the requirements of scientific evidence. Unlike medications, which almost always rely on randomized clinical trials to assess efficacy and safety, medical devices have no standardized methodology for determining the depth and scope of the clinical trials required. According to Nascimento [58], it is crucial for researchers to be aware of the regulatory environment before commencing a clinical trial involving a device. That is because even at the prototype or other development stages, the use of such devices presents risks that need to be assessed from both a health and ethical standpoint. This becomes crucial for ensuring research participants' safety and methodological quality to obtain data for future health registration [58].

In Brazil, patient access to new medical devices includes four macro-process stages [70]. Initially, ANVISA (Brazil's National Health Surveillance Agency) grants a health registration for the device to be marketed in the country. At this stage, access is restricted to people who can afford the expenses themselves, as it has not yet been incorporated into Brazilian Health System (SUS). For national reimbursement and funding policies, submitting and evaluating the device in technological incorporation processes is necessary. In the process of inclusion in the National Supplementary Health Agency (ANS) catalog, access is expanded but limited to the population covered by private health insurance, as Brazil's SUS has not yet granted it. Universal access by the population only occurs after deliberation by the National Commission for the Incorporation of Technologies into Brazilian Health System (CONITEC). Ultimately, for technologies to be used in health facilities, the local incorporation process must be considered through the process of acquisition and availability in the health services, thus representing effective access [75].

Thus, the process of incorporating technology into Brazil's SUS is the milestone that establishes the conditions for accessing and offering technologies to the Brazilian population. In other words, the medical device will only be purchased for use in the public health system if it passes this stage of incorporation into the SUS. For this process, CONITEC incorporates evaluation requirements, such as impact and sustainability, as well as the dimensions of efficacy, safety, and effectiveness, which are the responsibility of other agencies, such as ANVISA. Mastering the competencies related to the regulatory pathway of medical devices during the early stages of development enables compliance with technical and regulatory requirements and standards that will be demanded during the health registration process and the incorporation of technology into SUS later on [33, 63, 64, 76, 77]. This helps to minimize risks and uncertainties throughout the technology development process.

Regarding the essential skills for research teams, the findings highlight the need for collaboration with the industry and further regular and effective communication with managers, utilizers, patients, caregivers, and healthcare professionals. Concerning transdisciplinary themes, the study aligns with the literature in emphasizing the importance of fostering synergy between Health Technology Assessment units (HTAs) and the Technology Innovation Centers (TICs) of universities [63, 64, 78]. This articulation is crucial for anticipating demands and identifying opportunities that can accelerate the development of innovative solutions, contributing to the effectiveness and sustainability of healthcare services.

The formation of multidisciplinary teams, encouragement of entrepreneurship, establishment of partnerships, and the presence of certified laboratory infrastructures were identified by study participants as essential institutional capacities. To foster partnerships between universities and industry and to ensure that the knowledge generated by research groups is further effectively utilized by society, a new Legal Framework for Science, Technology, and Innovation was enacted in Brazil [79]. In summary, this framework encompasses a series of legal reforms designed to strengthen mechanisms for funding,

cooperation with companies, and licensing and technology transfer.

However, regarding laboratory infrastructure, it is possible to identify gaps through the National Research Infrastructure Platform (MCTI) [80]. For instance, the Platform indicates the existence of 33 vivariums installed in public institutions, accredited for experimentation by the Council for Animal Experimentation. Of these, only two animal facilities have the highest international certification from the Association for Assessment and Accreditation of Laboratory Animal Care. As for the clinical research centers in Brazil, the 2020 mapping carried out by Brazil's Ministry of Health points out that, although the country has reference centers, it still lacks an adequate number of institutions with quality infrastructure to carry out more complex phase I and II clinical trials, which require the densification of the entire Research, Development & Innovation (RD&I) chain [81]. In both scenarios, the data shows the necessity of mapping out and improving these structures so they comply with national and international regulatory requirements.

Conclusion

The learning gaps identified in this study can explain Brazil's low performance in the health innovation segment, and in particular, medical devices segment, considering that the training of human resources is a determining factor for the development of the innovation ecosystem. However, as Illeris [14] and Lundvall [3] emphasized, learning is interactive and is conditioned not only by individual knowledge, but also by institutional and cultural factors related to the country.

This study provides an original contribution by systematically identifying critical gaps in knowledge and competencies among Brazilian researchers in the medical device sector. Additionally, the validation of a theoretical model with three dimensions - knowledge, capacity, and institutional structure - represents an innovative approach to understanding the needs of the sector and proposing actionable strategies for improvement.

The learning gaps, the lack of qualified structures and the absence of certain institutional capacities, along with the fragility of the Brazilian industrial base, and the transformations brought about by the impact of the spread of the 4.0 revolution technologies, could increasingly accentuate the asymmetries between the innovations launched by major players and the capacity to make them available to the public health system, and consequently further aggravate the conditions of access to health care for the Brazilian population.

Among 102 surveyed researchers, less than 25% demonstrated strong expertise in key areas such as human factors engineering and usability (23%), patent and asset management (24%), pre-clinical and clinical trials (29%), and business planning (30%). Additionally, knowledge of regulatory requirements for incorporating technologies into Brazil's public health system (SUS) was limited, with only 31% reporting good proficiency. The study also identified significant disparities in infrastructure, with deficiencies in laboratory facilities and capabilities for conducting complex clinical trials. Despite recognizing the importance of multidisciplinary collaboration, most researchers reported limited interaction with stakeholders, such as healthcare professionals and managers, which is crucial for assessing the feasibility and implementation of medical devices.

Understanding the competencies and gaps to be overcome, both professional and institutional, can contribute to the adoption of more effective institutional strategies and public policies for training qualified teams. In addition, they also contribute to structuring more efficient environments for interaction with the relevant players, which are essential factors for advancing results in health innovation in Brazil.

Considering the need to advance in the qualification of the available infrastructure and, due to the diversity of technologies covered by the medical devices segment, which require different levels of complexity, the literature on successful trajectories points to the need to adopt specialization strategies and concentrate competitive efforts on sub-segments with greater technological intensity [82, 83].

Compared to previous studies, such as that by Nascimento *et al.* [58], which highlights deficiencies in laboratory infrastructure for early-phase clinical trials in Brazil, this study extends the discussion by providing specific data on researchers' self-perceived competencies. This alignment with prior research underscores the urgency of strengthening infrastructure and technical training to meet regulatory and technological demands.

This expertise would be especially useful in outlining a translational route and learning paths and strategies that seek to address the learning gaps and organizational shortcomings highlighted in this study, without losing sight of the real needs of Brazil's National Health System (SUS). It is therefore necessary to consider the education-health dyad as an intervention tool in this process, which also involves strengthening the Health Economic-Industrial Complex (HEIC) in Brazil.

The data from this study points to a convergence of responses regarding the importance and limited capacity of the technical and health regulatory areas and the incorporation of technology into the SUS. These are essential competencies for advancing the development of an innovative medical device and making it available to Brazilian society.

The challenge is to develop a set of professional and institutional skills that foster the ability to respond to the challenges of the public health system. Setting up teams capable of understanding and executing the translational research cycle could be one of the ways to speed up this process. Furthermore, it is necessary to analyze the list of structures and capacities to be developed by Brazilian institutions for the proper approach to public policy.

Another factor that may be decisive is the convergence of government action within the Health Economic-Industrial Complex in Brazil and the direction of the innovation system's efforts to meet the demands that affect the health system. The latter is present in the recently launched National Development Strategy for the Health Economic-Industrial Complex, which formalizes the Brazilian government's intention to guide this concentration of efforts, not around specific products, but around the health challenges for Brazil's National Health System (SUS) [84–86].

Due to the clear option to induce the innovation process by the demand of the SUS, it becomes even more necessary to formulate public policies and institutional strategies focused on the qualification of translational research teams for the adoption of good practices, from the initial phase of development of an innovative medical device, in order to contribute to the fulfillment of technical and regulatory requirements and standards that will be demanded in the process of sanitary registration and incorporation of the technology into the SUS.

The findings reveal a systemic need to improve education, training, and institutional support to advance translational research in Brazil. These results underscore the importance of aligning research and innovation efforts with public health needs, strengthening the Health Economic-Industrial Complex (HEIC), and fostering synergies between academia, industry, and government to accelerate the development and adoption of medical technologies in the SUS.

Public policies and institutional strategies should prioritize creating transdisciplinary teams, fostering collaboration with industry, and establishing environments that streamline compliance with technical and regulatory requirements. By addressing these gaps, Brazil can reduce the technological vulnerability of its health system and guarantee equitable access to essential health technologies.

The qualification of translational teams and the guidance of public policies and institutional strategies can be decisive in reducing the technological vulnerability of Brazil's SUS and guaranteeing the population's access to essential technologies for prevention, diagnosis, treatment and rehabilitation in health, as well as achieving the health-related Sustainable Development Goals. This qualification process must take into account articulated and programmatic actions involving universities, research institutions, companies, industry and research funding bodies.

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
Conceptualization, N.M., L.A. and R.V.; methodology, N.M., G.S., M.S.; software, G.S., M.S. and F.F.; validation, G.S., M.S., F.F. and R.V.; formal analysis, N.M., E.O. and F.T.; investigation, N.M.; resources, N.M.; data curation, F.F.; writing-original draft preparation, N.M.; writing-review and editing, N.M. L.A., E.O., F.T., E.J. and R.V.; visualization, N.M.; supervision, L.A. and R.V.; project administration, R.V.; funding acquisition, R.V. All authors have read and agreed to the published version of the manuscript.

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Data availability
The dataset analyzed for this study can be found in the Zenodo open access repository, available at: https://doi.org/10.5281/zenodo.10622263.

Declarations

Ethics approval and consent to participate
The online questionnaire used in this study was approved by the Research Ethics Committee of the Federal University of Rio Grande do Norte, Natal, Brazil, through letter; CAAE-No. 65474322.9.0000.5292, and in accordance with the Helsinki Accords (modified 2004). Consent to participate in this study was obtained implicitly through the survey.

Consent for publication
All authors of the manuscript have read and agreed with the publication of this version.

Competing interests
The authors declare no competing interests.

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References

1. DeChant AK, Fening S, Haag M, Harte W, Chance MR. Optimizing biomedical discoveries as an engine of culture change in an academic medical center. J Clin Transl Sci. 2022;6(1):e19. https://doi.org/10.1017/cts.2021.888.
2. Lundvall BA, Joseph KJ, Chaminade C, Vang J, editors. Handbook of Innovation Systems and Developing Countries. vol. 1. 1st ed. Northampton: Edward Elgar Publishing; 2009. https://doi.org/10.4337/9781849803427.
3. Lundvall BA. The Learning Economy and the Economics of Hope. vol. 1. 1st ed. London: Anthem Press; 2016. https://library.oapen.org/bitstream/handle/20.500.12657/31613/626406.pdf. Accessed 31 Jan 2024.
4. Guimarães R. Entrepreneurial Logic in health research. Cienc Saúde Coletiva. 2019;24(9):3571–82. https://doi.org/10.1590/1413-81232018249.10292019.
5. Christensen CM, Bohmer R, Kenagy J, et al. Will disruptive innovations cure health care? Harv Bus Rev. 2000;78(5):102–17.
6. Carayannis EG, Barth TD, Campbell DF. The Quintuple Helix innovation model: global warming as a challenge and driver for innovation. J Innov Entrep. 2012;1(1):2. https://doi.org/10.1186/2192-5372-1-2.
7. Carayannis EG, Campbell DF. Triple Helix, Quadruple Helix and Quintuple Helix and How Do Knowledge, Innovation and the Environment Relate To Each Other?: A Proposed Framework for a Trans-disciplinary Analysis of Sustainable Development and Social Ecology. Int J Soc Ecol Sustain Dev (IJSESD). 2010;1(1):41–69. https://doi.org/10.4018/jsesd.2010010105.
8. Sanami M, Flood T, Hall R, Kingscott F, Jayne D, Culmer P. Translating healthcare innovation from academia to industry. Adv Mech Eng. 2017;9(3):1687814017694114. https://doi.org/10.1177/1687814017694114.
9. Dutta S, Lanvin B, Rivera León L, Wunsch-Vincent S. Global Innovation Index 2023: Innovation in the face of uncertainty. 16th ed. Global Innovation Index. Geneva: World Intellectual Property Organization (WIPO); 2023. https://doi.org/10.34667/tind.48220.
10. Bori, Elsevier. 2023: ano de queda na produção científica de 35 países, inclusive o Brasil. 2023. https://abori.com.br/relatorios/producao-cientifica-no-br-cai-em-2023/. Accessed 10 Dec 2024.
11. De Negri F. New pathways for innovation in Brazil. vol. 1. 1st ed. Washington, DC: Wilson Center: Rio de Janeiro: Ipea; 2021. https://doi.org/10.38116/978-65-5635-021-9.
12. Nonaka I. A Dynamic Theory of Organizational Knowledge Creation. Organ Sci. 1994;5(1):14–37.
13. Nonaka I, Takeuchi H. Criação de conhecimento na empresa: como as empresas japonesas geram a dinâmica da inovação. vol. 1. 1st ed. Rio de Janeiro: Editora Campus; 1997.
14. Illeris K. Teorias contemporâneas da aprendizagem. 1st ed. Porto Alegre: Penso Editora; 2013.
15. Usher R. Experiência, pedagogia e práticas sociais. In: Illeris K, editor. Teorias contemporâneas da aprendizagem, vol. 1. Porto Alegre: Penso Editora; 2013. p. 199.
16. Figueiredo PN. National innovation strategy: A brief contribution to its effectiveness from the perspective of technological capability accumulation. Rev Adm Publica. 2023;57(5):e2022-0418. https://doi.org/10.1590/0034-761220220418.
17. Hörig H, Marincola E, Marincola FM. Obstacles and opportunities in translational research. Nat Med. 2005;11(7):705–8. https://doi.org/10.1038/nm0705-705.
18. Niederhuber JE. Translating Discovery to Patient Care. JAMA. 2010;303(11):1088–9. https://doi.org/10.1001/jama.2010.281.
19. Watts G. Lost in translation. BMJ. 2011;343:d7047. https://doi.org/10.1136/bmj.d7047.
20. Woolf SH. The Meaning of Translational Research and Why It Matters. JAMA. 2008;299(2):211–3. https://doi.org/10.1001/jama.2007.26.
21. Rubio DM, Schoenbaum EE, Lee LS, Schteingart DE, Marantz PR, Anderson KE, et al. Defining Translational Research: Implications for Training. Acad Med. 2010;85(3):470–5. https://doi.org/10.1097/ACM.0b013e3181ccd618.
22. Schulte PA, Cunningham TR, Nickels L, Felknor S, Guerin R, Blosser F, et al. Translation research in occupational safety and health: A proposed framework. Am J Ind Med. 2017;60(12):1011–22. https://doi.org/10.1002/ajim.22780.
23. Keramaris NC, Kanakaris NK, Tzioupis C, Kontakis G, Giannoudis PV. Translational research: From benchside to bedside. Injury. 2008;39(6):643–50. https://doi.org/10.1016/j.injury.2008.01.051.
24. CDC. Translation Research. 2018. Centers for Disease Control and Prevention (CDC) - The National Institute for Occupational Safety and Health (NIOSH). https://www.cdc.gov/niosh/topics/translationresearch/default.html. Accessed 15 Oct 2023.
25. Institute of Medicine. The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research. Washington, DC: The National Academies Press; 2013. https://doi.org/10.17226/18323.
26. Nicolescu B. A Evolução Transdisciplinar a Universidade Condição para o Desenvolvimento Sustentável. In: Chulalongkorn University, editor. A Responsabilidade da Universidade para com a Sociedade. vol. 1 of 1. International Association of Universities. Bangkok, Thailand: Chulalongkorn University: CIRET - Centre International de Recherches et études Transdisciplinaires; 1997. p. b12c8por. https://ciret-transdisciplinarity.org/bulletin/b12c8por.php. Accessed 10 Dec 2024.
27. Lottes AE, Cavanaugh KJ, Chan YYF, Devlin VJ, Goergen CJ, Jean R, et al. Navigating the Regulatory Pathway for Medical Devices–a Conversation with the FDA, Clinicians, Researchers, and Industry Experts. J Cardiovasc Transl Res. 2022;15(5):927–43. https://doi.org/10.1007/s12265-022-10232-1.
28. Marcus HJ, Payne CJ, Hughes-Hallett A, Marcus AP, Yang GZ, Darzi A, et al. Regulatory approval of new medical devices: cross sectional study. BMJ. 2016;353. https://doi.org/10.1136/bmj.i2587.
29. Schwartz J, Macomber C. So, You Think You Have an Idea: A Practical Risk Reduction-Conceptual Model for Academic Translational Research. Bioengineering. 2017;4(2):29. https://doi.org/10.3390/bioengineering4020029.
30. Gadelha CAG, Vargas MA, Alves NG. Translational research and innovation systems in health: implications on the biopharmaceutical segment. Saúde Debate. 2019;43(spe2):133–46. https://doi.org/10.1590/0103-11042019S210.
31. Guimarães R, Noronha J, Elias FTS, Gadelha CAG, Carvalheiro JDR, Ribeiro A. Policy for Science, Technology and Innovation in Health. Ciênc Saúde Coletiva. 2019;24(3):881–6. https://doi.org/10.1590/1413-81232018243.34652018.
32. Guimarães R. Translational research: an interpretation. Ciênc Saúde Coletiva. 2013;18(6):1731–44. https://doi.org/10.1590/S1413-81232013000600024.
33. Mayrink NNV, Alcoforado L, Chioro A, Fernandes F, Lima TS, Camargo EB, et al. Translational research in health technologies: A scoping review. Front Digit Health. 2022;4:957367. https://doi.org/10.3389/fdgth.2022.957367.
34. Le Boterf G. De la compétence à la navigation professionnelle. 1st ed. France: Les Éditions d'organisation. Fait partie d'un numéro thématique: Immigration; 1997.
35. Hendarman AF, Cantner U. Soft skills, hard skills, and individual innovativeness. Eurasian Bus Rev. 2018;8(2):139–69. https://doi.org/10.1007/s40821-017-0076-6.
36. Kyllonen PC. Soft Skills for the Workplace. Change Mag High Learn. 2013;45(6):16–23. https://doi.org/10.1080/00091383.2013.841516.
37. Robles MM. Executive Perceptions of the Top 10 Soft Skills Needed in Today's Workplace. Bus Commun Q. 2012;75(4):453–65. https://doi.org/10.1177/1080569912460400.
38. Gadelha CAG. Health Economic-Industrial Complex: the economic and material basis of the Brazilian Unified National Health System. Cad Saúde Pública. 2022;38:e00263321. https://doi.org/10.1590/0102-311X00263321.
39. Gadelha CAG. Saúde é desenvolvimento: o Complexo Econômico-Industrial da Saúde como opção estratégica nacional. vol. 1. 1st ed. Rio de Janeiro: Fiocruz - CEE: Centro de Estudos Estratégicos da Fiocruz Antonio Ivo de Carvalho (CEE); 2022.
40. Gadelha CAG, Temporão JG. Development, Innovation and Health: the theoretical and political perspective of the Health Economic-Industrial Complex. Ciênc Saúde Coletiva. 2018;23(6):1891–902. https://doi.org/10.1590/1413-81232018236.06482018.
41. Buss PM, Chamas C, Faid M, Morel C. Development, health, and international policy: the research and innovation dimension. Cad Saúde Pública. 2016;32:e00046815. https://doi.org/10.1590/0103-311X00046815.

42. Maldonado J, Gadelha CAG, Costa LS, Vargas M. The innovative dynamic of the mechanics, electronics and materials subsystem. Rev Saúde Pública. 2012;46:29–36. https://doi.org/10.1590/S0034-89102012000700005.
43. Maldonado J, Gadelha CAG, Vargas M. O subsistema de base mecânica, eletrônica e de materiais do complexo econômico industrial da saúde: perspectivas para 2022/2030. Broy M, Denert E, editors. Rio de Janeiro: Fiocruz/Ipea/Ministério da Saúde/Secretaria de Assuntos Estratégicos da Presidência da República: Scielo Books; 2013.
44. World Health Organization. World report on knowledge for better health: strengthening health systems. 2004. World Health Organization, Geneva PP - Geneva [Online]. https://apps.who.int/iris/handle/10665/43058. Accessed 10 Dec 2024.
45. World Health Organization. Emerging technologies and scientific innovations: A global public health perspective. 2023. https://www.who.int/publications/i/item/9789240073876. Accessed 10 Dec 2024.
46. World Health Organization. Local Production and Technology Transfer to Increase Access to Medical Devices — Addressing the barriers and challenges in low- and middle- income countries. 2012. https://www.who.int/publications/i/item/9789241504546. Accessed 31 Jan 2024.
47. World Health Organization. Development of medical device policies. (WHO Medical device technical series). 2011. https://iris.who.int/bitstream/handle/10665/44600/9789241501637-eng.pdf. Accessed 31 Jan 2024.
48. World Health Organization. Global atlas of medical devices 2022. 2022. https://www.who.int/publications/i/item/9789240062207. Accessed 10 Dec 2024.
49. United Nations. Take Action for the Sustainable Development Goals. New York; 2015. https://www.un.org/sustainabledevelopment/sustainable-development-goals/. Accessed 25 Mar 2024.
50. World Health Organization. Human resources for medical devices, the role of biomedical engineers (WHO Medical device technical series). 2017. https://iris.who.int/bitstream/handle/10665/255261/9789241565479-eng.pdf. Accessed 31 Jan 2024.
51. Fernández-Arias P, Anton-Sancho Á, Vergara D, Barrientos A. Soft Skills of American University Teachers: Self-Concept. Sustainability. 2021;13(22):12397. https://doi.org/10.3390/su132212397.
52. Al-Sa'di A, Yamjal P, Ahmad E, Panjabi R, Allott McPhee C, Guler O. Assessing Educators' Soft Skills: Developing a Self-Assessment Instrument. Adm Sci. 2023;13(9):208. https://doi.org/10.3390/admsci13090208.
53. Anton-Sancho A, Vergara D, Fernández-Arias P. Self-Assessment of Soft Skills of University Teachers from Countries with a Low Level of Digital Competence. Electronics. 2021;10(20):2532. https://doi.org/10.3390/electronics10202532.
54. Brasil. Pesquisa de Saúde. 2024. http://pesquisasaude.saude.gov.br/pesquisas.xhtml. Accessed 01 Feb 2024.
55. CNPQ. Consulta parametrizada — Diretório dos Grupos de Pesquisa no Brasil — Conselho Nacional de Desenvolvimento Científico e Tecnológico. 2024. https://dgp.cnpq.br/dgp/faces/consulta/consulta_parametrizada.jsf. Accessed 01 Feb 2024.
56. Brasil. pePI — Pesquisa em Propriedade Industrial — Instituto Nacional da Propriedade Industrial — Ministério da Economia. 2024. https://busca.inpi.gov.br/pePI/jsp/patentes/PatenteSearchBasico.jsp. Accessed 01 Feb 2024.
57. Bardin L. Análise de Conteúdo. 1st ed. São Paulo: Edições 70/Almedina Brasil; 2016.
58. Nascimento AFD. Analysis of the impact of clinical evaluation on the submissions of high risk medical devices to the Brazilian Health Regulatory Agency. Health Surveill Under Debate Soc Sci Technol. 2019;7(2):37–45. https://doi.org/10.22239/2317-269x.01231.
59. Anderson JR, Chung TDY, Clark L, Weis JA, Danielsen AJ, Khosla S, et al. Translation to Practice: Accelerating the Cycle of Innovation to Impact. Mayo Clin Proc. 2019;94(3):490–9. https://doi.org/10.1016/j.mayocp.2018.08.008.
60. Felipe MSS, Rezende KS, Rosa MFF, Gadelha CAG. A look at the Industrial Economic Health Complex and Translational Research. Saúde Debate. 2019;43(123):1181–93. https://doi.org/10.1590/0103-1104201912316.
61. Lupatini EDO, Barreto JOM, Zimmermann IR, Silva END. Medicines and translational research: steps, actors, and health policies in the Brazilian context. Saúde Debate. 2019;43(spe2):181–99. https://doi.org/10.1590/0103-11042019S214.
62. Berro M, Burnett BK, Fromell GJ, Hartman KA, Rubinstein EP, Schuff KG, et al. Support for Investigator-Initiated Clinical Research Involving Investigational Drugs or Devices: The Clinical and Translational Science Award Experience. Acad Med. 2011;86(2):217–23. https://doi.org/10.1097/ACM.0b013e3182045059.
63. Levin L, Sheldon M, McDonough RS, Aronson N, Rovers M, Gibson CM, et al. Early technology review: towards an expedited pathway. Int J Technol Assess Health Care. 2024;40(1):e13. https://doi.org/10.1017/S0266462324000047.
64. Blankart CR, Dams F, Penton H, Kaló Z, Zemplényi A, Shatrov K, et al. Regulatory and HTA early dialogues in medical devices. Health Policy. 2021;125(10):1322–9. https://doi.org/10.1016/j.healthpol.2021.07.010.
65. Lievevrouw E, Marelli L, Van Hoyweghen I. The FDA's standard-making process for medical digital health technologies: co-producing technological and organizational innovation. BioSocieties. 2022;17(3):549–76. https://doi.org/10.1057/s41292-021-00232-w.
66. Bano R, Gupta S, Shekhar C. Translational research in biomedical sciences in India: Challenges, observations & national perspectives. Indian J Med Res. 2020;152(4):335–41. https://doi.org/10.4103/ijmr.IJMR_1296_19.
67. Pitzen JH, Dieter HL, Gronseth DL, Dahl AK, Boyle VL, Maran T, et al. Transforming the practice of medicine through team science. Health Res Policy Syst. 2020;18(1):104. https://doi.org/10.1186/s12961-020-00619-4.
68. Borton DA, Dawes HE, Worrell GA, Starr PA, Denison TJ. Developing Collaborative Platforms to Advance Neurotechnology and Its Translation. Neuron. 2020;108(2):286–301. https://doi.org/10.1016/j.neuron.2020.10.001.
69. Tellez A, Ferrone M, Granada JF. Translational Research: The Cornerstone for Medical Technology Advancement. Toxicol Pathol. 2019;47(3):203–4. https://doi.org/10.1177/0192623318819972.
70. Conto M, Bonan LFS. Legal framework of adoption and access of medical devices in Brazil: structure, types of assessment and opportunities for advances. J Bras Econ Saúde. 2020;12(3):213–25. https://doi.org/10.21115/JBES.v12.n3.p213-25.
71. Ferreira-Da-Silva AL, Ribeiro RA, Santos VCC, Elias FTS, d'Oliveira ALP, Polanczyk CA. Guidelines for budget impact analysis of health technologies in Brazil. Cad Saúde Pública. 2012;28(7):1223–38. https://doi.org/10.1590/S0102-311X2012000700002.
72. Brasil. O uso de limiares de custo-efetividade nas Decisões em Saúde: Recomendações da Comissão Nacional de Incorporação de Tecnologias no SUS. 2022. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Departamento de Ciência e Tecnologia. https://www.gov.br/conitec/pt-br/midias/pdf/2022/20221106_relatorio-uso-de-limiares-de-custo-efetividade-nas-decisoes-em-saude.pdf. Accessed 10 Dec 2024.
73. Campolina AG, Yuba TY, Soárez PCD. Decision criteria for resource allocation: an analysis of CONITEC oncology reports. Ciênc Saúde Coletiva. 2022;27(7):2563–72. https://doi.org/10.1590/1413-81232022277.14242021.
74. Brasil. Diretrizes Metodológicas: Diretriz de Avaliação Econômica - 2a edição. 2014. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. https://www.gov.br/conitec/pt-br/midias/artigos_publicacoes/diretrizes/diretriz-de-avaliacao-economica.pdf. Accessed 10 Dec 2024.
75. Toscas FS. Approaches to horizon scanning and technological prospecting in medical devices. J Bras Econ Saúde. 2021;13(3):236–41. https://doi.org/10.21115/JBES.v13.n3.p236-41.
76. Tarricone R, Torbica A, Drummond M. Challenges in the Assessment of Medical Devices: The MedtecHTA Project. Health Econ. 2017;26(S1):5–12. https://doi.org/10.1002/hec.3469.
77. Pecchia L, Craven MP. Early stage Health Technology Assessment (HTA) of biomedical devices. The MATCH experience. In: Long M, editor. World Congress on Medical Physics and Biomedical Engineering May 26-31, 2012, Beijing, China. Berlin: Springer Berlin Heidelberg; 2013. pp. 1525–8. https://doi.org/10.1007/978-3-642-29305-4_401.
78. Tummers M, Kværner K, Sampietro-Colom L, Siebert M, Krahn M, Melien O, et al. On the integration of early health technology assessment in the innovation process: reflections from five stakeholders. Int J Technol Assess Health Care. 2020;36(5):481–5. https://doi.org/10.1017/S0266462320000756.

79. Brasil. DECRETO N° 9.283, DE 7 DE FEVEREIRO DE 2018. 2018. https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/decreto/d9283.htm. Accessed 01 Feb 2024.
80. Brasil. Plataforma Nacional de Infraestrutura de Pesquisa MCTI. 2024. https://pnipe.mcti.gov.br/. Accessed 10 Dec 2024.
81. Brasil. Plano de Ação de Pesquisa Clínica no Brasil. 2020. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Departamento de Ciência e Tecnologia. https://bvsms.saude.gov.br/bvs/publicacoes/plano_acao_pesquisa_clinica_brasil.pdf. Accessed 01 Feb 2024.
82. Hu F, Qiu L, Zhou H. Medical Device Product Innovation Choices in Asia: An Empirical Analysis Based on Product Space. Front Public Health. 2022;10:871575. https://doi.org/10.3389/fpubh.2022.871575.
83. Carvalho ARd, Gala P. Brasil, uma economia que não aprende: novas perspectivas para entender nosso fracasso. vol. 1. 1st ed. São Paulo: E-book; 2020. https://www.paulogala.com.br/wp-content/uploads/2020/06/BRASIL-nao-aprende-Cortesia-PDF-1.pdf. Accessed 01 Feb 2024.
84. Brasil. DECRETO N° 11.715, DE 26 DE SETEMBRO DE 2023. 2023. https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/D11715.htm. Accessed 01 Feb 2024.
85. Brasil. PORTARIA GM/MS N° 1.354, DE 27 DE SETEMBRO DE 2023. 2023. https://www.in.gov.br/web/dou/-/portaria-gm/ms-n-1.354-de-27-de-setembro-de-2023-513060106. Accessed 01 Feb 2024.
86. Brasil. PORTARIA GM/MS N° 2.261, DE 8 DE DEZEMBRO DE 2023. 2023. https://www.in.gov.br/en/web/dou/-/portaria-gm/ms-n-2.261-de-8-de-dezembro-de-2023-529259361. Accessed 10 Dec 2024.

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