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ORIGINAL ARTICLE

Public Consultation SECTICS/MS No. 69/2025: Challenges and opportunities for strengthening clinical research in Brazil

Consulta Pública Sectics/MS nº 69/2025: desafios e oportunidades para o fortalecimento da pesquisa clínica no Brasil

Consulta Pública SECTICS/MS nº 69/2025: desafíos y oportunidades para el fortalecimiento de la investigación clínica en Brasil

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ABSTRACT This study analyses data from the Public Consultation SECTICS/MS No. 69/2025, conducted by the Ministry of Health as part of an assessment of the current state of the clinical research ecosystem in Brazil. It is an observational study with both quantitative and qualitative approaches. Data collection took place from August 4 to September 18, 2025, through the Participa + Brasil platform. A semi-structured questionnaire with 65 questions organized into 10 thematic blocks was used. Of the 114 participants, most were from the Southeast and South regions. The main challenges identified were bureaucratic complexity and regulatory delays (85 mentions), insufficient funding (55), regional disparities in infrastructure (53), and a shortage of qualified professionals (52). The most frequently cited opportunities included regulatory improvement (65), training and capacity-building (47), digital integration (45), and strengthening research infrastructure. Criticism focused on the research ethics review system, particularly regarding the instability of the Plataforma Brasil. The findings indicate that the Brazilian clinical research ecosystem is undergoing consolidation, still marked by regional asymmetries, regulatory bottlenecks, and financial fragility.

KEYWORDS Clinical study. National Science, Technology and Innovation Policy. Unified Health System. Brazil.

RESUMO *Este estudo analisa dados provenientes da Consulta Pública Sectics/MS nº 69/2025, conduzida pelo Ministério da Saúde como parte de um diagnóstico da situação atual do ecossistema de pesquisa clínica no Brasil. Trata-se de um estudo observacional com abordagens quantitativa e qualitativa. A coleta de dados ocorreu entre 4 de agosto e 18 de setembro de 2025, por meio da plataforma Participa + Brasil. Utilizou-se um formulário semiestruturado composto por 65 questões, organizadas em 10 blocos temáticos. Dos 114 participantes, a maioria era das regiões Sudeste e Sul. Os principais desafios identificados foram a burocracia e a lentidão regulatória (85 menções), a insuficiência de financiamento (55), as desigualdades regionais de infraestrutura (53) e a escassez de profissionais especializados (52). As oportunidades mais citadas incluíram o aprimoramento regulatório (65), a formação e capacitação (47), a integração digital (45) e o fortalecimento da infraestrutura. Foram registradas críticas ao sistema ético, especialmente devido à instabilidade da Plataforma Brasil. Os achados indicam um ecossistema de pesquisa clínica em consolidação, ainda marcado por assimetrias regionais, entraves regulatórios e fragilidade no financiamento.*

PALAVRAS-CHAVE *Estudo clínico. Política Nacional de Ciência, Tecnologia e Inovação. Sistema Único de Saúde. Brasil.*

RESUMEN *Este estudio analiza los datos de la Consulta Pública SECTICS/MS Nº 69/2025, realizada por el Ministerio de Salud como parte de un diagnóstico sobre la situación actual del ecosistema de investigación clínica en Brasil. Se trata de un estudio observacional con enfoques cuantitativo y cualitativo. La recolección de datos se llevó a cabo entre el 4 de agosto y el 18 de septiembre/2025, en la plataforma Participa + Brasil. Se utilizó un cuestionario semiestructurado con 65 preguntas organizadas en 10 bloques temáticos. De los 114 participantes, la mayoría procedía de las regiones Sudeste y Sur. Los principales desafíos identificados fueron la burocracia y la lentitud regulatoria (85 menciones), la insuficiencia de financiamiento (55) y las desigualdades regionales en infraestructura (53). Las oportunidades más mencionadas incluyeron el fortalecimiento del marco regulatorio (65), la formación y capacitación (47) y el refuerzo de la infraestructura. Se registraron críticas al sistema ético por la inestabilidad de la Plataforma Brasil. Los hallazgos indican que el ecosistema de investigación clínica en Brasil se encuentra en proceso de consolidación, aunque aún está marcado por asimetrías regionales, trabas regulatorias y fragilidad financiera.*

PALABRAS CLAVE *Estudio clínico. Política Nacional de Ciencia, Tecnología e Innovación. Sistema Único de Salud. Brasil.*

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Introduction

Clinical research encompasses studies involving human participants that seek to address clinical questions related to diagnosis, treatment, and patient management[1]. In addition to enabling the assessment of the safety, efficacy, effectiveness, and value of health interventions, clinical research constitutes a key component of national science, technology, and innovation systems in health[2]. It differs from health research in its focus on producing evidence directly applicable to clinical care, health technology incorporation, and health decision-making. In this context, clinical research plays a strategic role by articulating knowledge production and scientific, technological, and productive development, promoting innovation in health and expanding the population's access to safe and effective therapies[3].

In Brazil, this field assumes additional relevance because of the characteristics of the Unified Health System (SUS), which requires evidence-based solutions to respond to complex epidemiological challenges, reduce regional inequalities, and expand access to safe, effective, and cost-effective technologies. Moreover, the national capacity to design, coordinate, and conduct clinical studies is directly associated with the country's scientific and technological sovereignty, the attraction of investment, and Brazil's integration into global research and development networks[4].

The consolidation of this field in the country has been guided by a set of public policies and regulatory frameworks that structure both the ethical and health regulatory environment and the mechanisms for funding, training, and organizing research networks[4]. In this process, the Department of Science and Technology of the Secretariat of Science, Technology and Innovation in Health of the Ministry of Health (DECIT/SCTIE/MS) plays a key role. Its institutional mission includes promoting scientific and technological advancement and innovation in health in Brazil, in accordance with the competencies established in Article 35 of Decree Nº 11.798 of November 28, 2023[5].

In this context, the MoH established the Action Plan for Clinical Research in Brazil through Ordinance Nº 559 of March 9, 2018[6], in order to expand the national capacity to develop and attract clinical research. Its formulation was based on the assessment resulting from the Forum 'Clinical Research in Brazil: International Competitiveness and Challenges', promoted by the MoH in October 2016, which gathered representatives from several sectors to discuss the national landscape and identify opportunities for sector expansion. Following the Forum, structured listening meetings were conducted with the main stakeholders in the field. The final version of the Plan[7] was published in Portuguese and English and organized into six strategic axes: 1) Ethical Regulation; 2) Health Regulation; 3) Scientific and Technological Funding; 4) Training in Clinical Research; 5) National Clinical Research Network (RNPC); and 6) Knowledge Management.

More recently, in the context of the renewed emphasis on industrial and innovation policies in the country, Nova Indústria Brasil (NIB) was launched in 2024 as a systemic neoindustrialization policy with a policy horizon extending to 2026. Structured within the National Industrial Development Council (CNDI), the NIB is grounded in three central premises: the strategic role of industry in sustainable development; recognition of the premature deindustrialization and the weakened domestic production chains; and the low technological complexity of Brazilian exports. In the field of health, Mission 2 stands out, aimed at strengthening the Health Economic-Industrial Complex (CEIS), in which clinical research assumes a structuring role by articulating knowledge generation, technological development, and the incorporation of innovations into the SUS. By promoting integration among scientific

institutions, teaching hospitals, the productive sector, and regulatory bodies, the NIB expands the national capacity to conduct clinical studies, internalize strategic technologies, and reduce external dependence, while facilitating Brazil's insertion into global health value chains.

Despite the advances observed in the structuring of regulatory frameworks and funding instruments, the Brazilian clinical research ecosystem continues to face operational and institutional challenges. In this context, a technical assessment of the actions implemented in the five years following the publication of the Action Plan was conducted to evaluate the implementation trajectory of the proposed strategies and identify persistent gaps. This assessment served a strategic purpose by systematizing the implemented initiatives and identifying the main obstacles to their effective implementation.

The evidence that these challenges exceed strictly normative dimensions, requiring broader stakeholder and public engagement processes, supported the MoH's launch of SECTICS/MS Public Consultation N°69/2025. This initiative became a key instrument for participatory assessment and the revision of sectoral guidelines, strengthening governance and enhancing the capacity of public policies for clinical research in the country.

Given this context, the present article analyzes data from the aforementioned public consultation, identifying and systematizing the main challenges and opportunities identified by different stakeholders in the Brazilian clinical research ecosystem. As the first formal public consultation initiative specifically directed at this topic, the study contributes to filling a relevant gap in participatory evidence, while also offering an updated assessment of this ecosystem. In doing so, it contributes to the contemporary debate on strengthening clinical research in the country, providing technical and scientific inputs for improving strategies and public policies in the field.

Material and methods

This is an observational, cross-sectional study with descriptive quantitative and exploratory qualitative components. SECTICS/MS Public Consultation Nº 69/2025 aimed to characterize the current scenario and the main challenges in conducting clinical research in Brazil, considering structural, ethical, and regulatory aspects, as well as the existing capacity of research centers. It aimed to gather input from a broad spectrum of stakeholders and institutions active or interested in the Brazilian clinical research ecosystem for more in-depth technical analyses and the formulation of a proposal to update the Action Plan for Clinical Research in Brazil from a medium- and long-term perspective.

Participants from different segments of the clinical research ecosystem were considered eligible, including health professionals and representatives of clinical research sponsors; researchers and investigators; Contract Research Organizations (CROs); participants in clinical research; and clinical research centers. Participants were invited to register on the Participa + Brasil platform, a federal government website designed to promote social participation in the construction and improvement of public policies. This platform has protected access mechanisms through username and password authentication.

A semi-structured questionnaire was developed for data collection, which included 33 closed-ended questions with predefined alternatives and 32 open-ended questions that allowed qualitative aspects to be explored. This instrument was structured into 10 blocks, namely: Block 1 – Respondent Identification; Block 2 – Institutional Module; Block 3 – Diagnosis of the Clinical Research Environment in Brazil; Block 4 – Proposals for Strengthening Clinical Research; Block 5 – Brazilian Clinical Research Ecosystem; Block 6 – Strengthening the Industrial Sector; Block 7 – Innovative Clinical Trials; Block 8 – International Models and Financing; Block

9 – Equity, Diversity, and Inclusion (EDI) Policies; and Block 10 – Final Comments.

The form was developed based on the analysis of normative and strategic documents related to Brazilian clinical research, including the Action Plan for Clinical Research[7] and the National Policy on Science, Technology, and Innovation in Health (PNCTIS)[8], as well as a literature review on clinical research ecosystems and science, technology, and innovation policies in health. Its structure included key dimensions such as regulation, financing, workforce training, infrastructure, governance, and network articulation. The instrument was submitted to internal validation by experts and managers in the field to ensure clarity, relevance, and comprehensiveness. Next, a pilot test was conducted in a controlled environment of the Participa + Brasil platform, enabling adjustments to the wording, navigation logic, and organization of the questions before the questionnaire was made publicly available.

The launch of the consultation was announced on July 30, 2025, through publication in the Official Gazette of the Union (DOU), and contributions were received over 46 consecutive days, between August 4 and September 18, 2025. For analytical purposes, a de-identified database in CSV format was extracted from the Participa + Brasil platform, to prevent the direct or indirect identification of participants. Access to this database was restricted to two authors of this manuscript, who were responsible for systematizing, processing, and analyzing the data. These data may be made available, in de-identified format, upon formal request to DECIT/SCTIE/MS, subject to compliance with the applicable ethical, regulatory, and legal provisions. The analyses were designed based on quantitative and qualitative approaches, as detailed below.

Quantitative approach

The quantitative analysis was performed using R software (version 4.4.3), with the RStudio interface (version 2024.12.1). The variables included respondent characteristics (individual and institutional profile), perceptions of the Brazilian clinical research environment, assessment of structural dimensions (regulation, financing, infrastructure, workforce training, governance, and network coordination), and proposals to strengthen the sector. The variables were mostly categorical, derived from closed-ended questions with predefined alternatives.

Descriptive analyses were performed, with calculation of absolute and relative frequencies for categorical variables. Where relevant, stratified analysis were conducted by type of respondent or institutional segment to identify differentiated response patterns. The results were presented through tables, figures, and cartographic representations. The maps were produced using QGIS software, version 3.44. No inferential analyses were performed due to the exploratory nature of the study and the non-probabilistic nature of the sample. Potential selection bias due to voluntary participation was acknowledged, limiting the generalizability of the findings.

Qualitative approach

The thematic axes were identified through an iterative analytical process, based on Bardin's[9] content analysis framework, combining a priori categories guided by the literature review and the dimensions of the data collection instrument with emergent categories derived from the empirical corpus, consisting of the responses submitted on the Participa + Brasil platform in the context of SECTICS/MS Public Consultation Nº 69/2025.

Content analysis comprises a set of techniques for analyzing communications through systematic and objective procedures for describing message content, developed in three main phases: i) pre-analysis, which involved an initial exploratory reading and organization of the material; ii) exploration of the material, with selection of the recording and context units relevant to the study

objective; and iii) treatment of results, categorization, and interpretation, in which thematic categories and subcategories were formed, enabling analysis and synthesis of the emerging meanings. This analysis was conducted systematically for each of the 32 open-ended questions, ensuring traceability between the data and the categories constructed, as well as coherence among the thematic axes identified, the theoretical framework adopted, and the study's objectives.

During the exploratory phase, a large language model (LLM), specifically ChatGPT (powered by GPT-5, professional version, OpenAI), was used as a support tool for textual data analysis. To this end, a structured, previously defined prompt was used with the aim of identifying recurring patterns, performing thematic grouping, and supporting the initial categorization of contributions (*table 1*). The model was used solely as an auxiliary and exploratory tool and did not replace the interpretive analysis conducted by the researchers. The analytical categories were developed iteratively and reflexively, with continuous review in light of the original corpus.

Table 1. Structured prompt used for exploratory qualitative analysis and thematic grouping of contributions submitted to Public Consultation SECTICS/MS Nº 69, Brazil, 2025

Structured prompt for exploratory qualitative analysis
Objectives • Identify recurring patterns in the responses to the question under analysis. • Group contributions into coherent thematic categories. • Analyze responses by respondent segment. • Identify overall and segment-specific trends. • Develop an integrated qualitative and quantitative analysis. • Extract specific insights related to the question under analysis.
Instructions
1. Scope of the analysis • Consider exclusively the responses associated with the question under analysis. • Do not incorporate content from other questions. • Use respondent segments as the primary analytical variable.
2. Qualitative thematic analysis • Read all responses in their entirety. • Identify recurring core themes related to the question. • Group responses into coherent thematic categories, providing an analytical rationale. • Identify subthemes within each category. • Highlight patterns, areas of convergences, and areas of divergences among respondents.

3. Segmented analysis
• Analyze responses byrespondent segments.
• Do not combine responses from different segments without explicitly acknowledging the distinction between them.
• Identify:
  • Overalltrends shared across multiple segments.
  • Segment-specific trends.
• Indicate which segments contribute most prominently to each thematic category.

4. Quantitative analysis (when applicable) • For closed-ended or mixed-format questions, reportthe number of responses by segment. • Integrate quantitative findings with the qualitative findings for the same question.
5. Semantic analysis and clustering • Generate semantic vector representations of the responses using appropriate methods (e.g., Word2Vec, BERT, or equivalent). • Apply clustering methods to identify emerging thematic groups. • Describe each cluster and its core content. • Indicate which respondent segments are most strongly associated with each cluster.

Table 1. Structured prompt used for exploratory qualitative analysis and thematic grouping of contributions submitted to Public Consultation SECTICS/MS Nº 69, Brazil, 2025

Structured prompt for exploratory qualitative analysis
6. Analysis of feelings (when applicable) • Classify responses as positive, negative, or neutral. • Identify variations in sentiment across respondent segments.
7. Extraction of insights • Identify the key findings regarding the question under analysis. • Highlight key challenges, gaps, and opportunities. • Identifyrecurring themes across different segments.
8. Limitations • Identify specific limitations of the analysis of the question (e.g., low response rate, concentration of responses within a single segment, or ambiguous responses).
Expected output (for each question) • Identified thematic categories. • Analytical description of each category. • Associated subthemes. • Representative anonymized examples. • Distribution by respondent segment. • Quantitative results by respondent segment, when applicable. • Identified semantic clusters. • Sentiment analysis, when applicable. • Interpretive synthesis of findings for the question under analysis. • Key challenges, gaps, and opportunities. • Analysis limitations.

Source: Prepared by the authors.

The results generated with support from the LLM were subjected to critical analysis, validation, and refinement by the research team, including adjustment of the categories and verification of consistency with the data, in order to ensure analytical rigor, traceability of inferences, and methodological control over the findings produced. The team was composed of researchers with experience in the management and formulation of public health policies, whose institutional practice and prior knowledge of the field were considered as part of the reflexive data interpretation process.

Pursuant to Article 26 of CNS/MS Resolution Nº 674/2022[10], public opinion surveys with non-identifiable participants are exempt from review by a Research Ethics Committee (REC), and therefore submission for formal ethical evaluation was not required. The data were used exclusively for analysis and to inform public policies aimed at strengthening clinical research in Brazil, respecting personal data protection standards, in accordance with Law Nº 13.709/2018[11] – the General Personal Data Protection Law (LGPD).

Results

A total of 114 participants responded to the questionnaire, of whom 61.4% did so out of their own interest and 38.6% represented institutions. Among the individual responses, clinical research professionals predominated (n=29), followed by those working in clinical research centers (24), health professionals (15), hospitals (15), and research institutions (14). Among the institutional responses, industries and their associations stood out (15), followed by clinical research centers (9) and research institutions (4). Other respondent categories, represented in smaller numbers, included research ethics professionals (7),

public managers (4), medical device industries or associations (3), research ethics oversight bodies (2), investors (2), and a health regulation specialist (1), in addition to other categories (10) (*graph 1*).

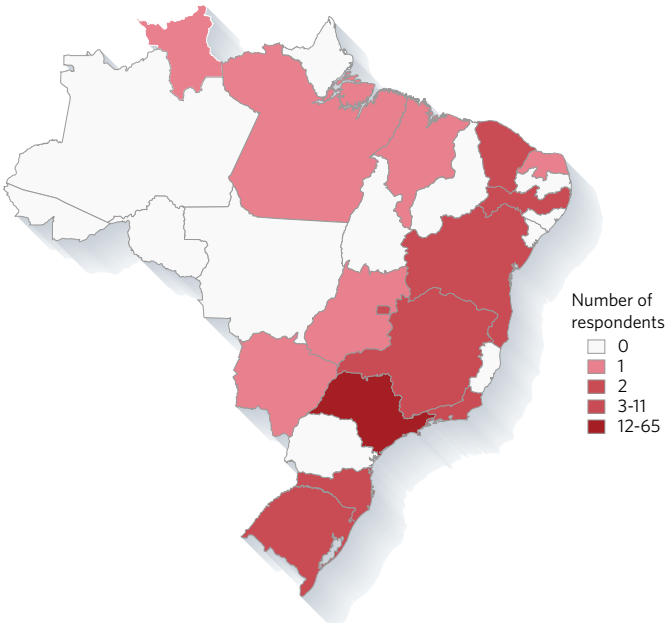
Graph 1. Profile of respondents by professional category and type of participation in Public Consultation SECTICS/MS Nº 69, Brazil, 2025

Source: Prepared by the authors.

Regarding the nature of the institutions represented, five broad stakeholder segments were identified: education and research institutions; industry and associated services (such as representative organizations and CROs); government and regulation; civil society; and other ecosystem stakeholders.

Figure 1 presents the distribution of respondents by state and region, showing the predominance of the Southeast and South regions, especially the state of São Paulo, which concentrated the largest number of responses. Next were the states of Rio de Janeiro, Minas Gerais, and Rio Grande do Sul. Lower levels of participation were observed in other regions, including the Federal District, Pernambuco, Bahia, Ceará, and Pará, reflecting the historical pattern of concentration of clinical research capacities along the Southeast-South axis and pointing to the need for strategies for regional decentralization and strengthening of scientific infrastructure.

Figure 1. Distribution of respondents by Federative Unit and region in Public Consultation SECTICS/MS Nº 69, Brazil, 2025



Source: Prepared by the authors.

Regarding the accumulated experience in clinical research, participants most frequently reported involvement in Phase III studies (86 mentions), followed by Phase II studies (74) and observational studies (71). Non-regulatory academic research (48 mentions) also stood out, reflecting the relevant role of universities and public institutes in producing evidence applicable to the SUS. Although less frequent, mentions of advanced therapies (45) and regulatory trials for registration (41) indicate the presence of specialized centers in biotechnology and gene therapy with capacity to operate at the technological frontier.

The main challenges for strengthening Brazilian clinical research, as pointed out by respondents, clustered around four structuring axes: bureaucratic complexity and regulatory delays (85 mentions); insufficient public and private financing (55); regional infrastructure inequalities (53); and shortage of specialized professionals (52). Other challenges included the country's low attractiveness to international sponsors, institutional fragmentation, and regulatory complexity that hinders coordination between ethical and health regulatory bodies.

By contrast, the main opportunities identified converge around five central themes: improvement of the regulatory environment (65 mentions); investment in training and capacity-building (47); integration of systems and digital platforms (45); public-private partnerships (41); and strengthening of national infrastructure (33). Other emerging themes included the use of innovative technologies, expansion of financing sources, and harmonization with international standards.

The results were synthesized in *figure 2*, which presents the strategic macro-themes and their thematic descriptions. These axes are structured around five complementary dimensions: 1) regulatory environment, highlighting normative clarity, transparent timelines, and ethical strengthening; 2) decentralized and integrated infrastructure, focusing on regional hubs, center certification, and interoperable technologies; 3) equity and diversity in clinical research, addressing the inclusion of underrepresented populations and regional balance; 4) sustainable and diversified financing, encompassing dedicated funds, tax incentives, and support for young researchers; and 5)

innovation and internationalization, emphasizing advanced therapies, global multicenter trials, and translation of evidence into public policies.

Figure 2. Strategic macro-themes identified from the analysis of responses to Public Consultation SECTICS/MS Nº 69, Brazil, 2025

Source: Prepared by the authors.

Assessment of the health regulatory process were relatively evenly distributed: 37.7% of respondents expressed a positive assessment; 32.5%, a negative assessment; and 29.8%, a neutral assessment. In this item, participants were invited to provide brief comments. Although they recognized recent institutional advances, the responses emphasized persistent bottlenecks related to lengthy timelines, bureaucracy, shortage of human resources, and overlapping competencies. The assessment of the research ethics review process for conducting clinical research was mostly critical: 46% of responses were negative; 34%, positive; and 20%, neutral. The main criticisms concerned the instability of Plataforma

Brasil and the lack of standardization among RECs, especially in procedures involving the National Research Ethics Commission (CONEP). Despite these limitations, participants recognized the Brazilian ethical system's robustness and its essential role in protecting research participants.

In the field of strengthening governance, the need for integration of databases and information systems stood out (83 mentions); the definition of joint plans and goals (70); monitoring and evaluation of results (47); and the active participation of researchers and research participants (45). Ideal governance was described as more coordinated, digital, and transparent, emphasizing accountability and interinstitutional collaboration. The most frequently cited practical actions to improve governance included forming partnerships with the private sector (71), implementing integrated digital platforms (61), technical capacity-building (54), technological modernization (54), and public financing (47).

Process optimization stood out (80 mentions) among the priority measures to improve the regulatory environment, followed by integration between ethical and health regulation (64), regulatory harmonization (50), and training of professionals in the regulatory field (42). The need for better communication between regulators and researchers, greater transparency, and adoption of risk-based approaches, aligned with international good practices, was also mentioned.

Regarding workforce training, there was broad agreement on the importance of continuous and certified capacity-building. The most frequent proposals included offering public courses and training programs (57), creating training pathways with certification in Good Clinical Practice (GCP), and expanding partnerships between academia and research centers (49). International exchanges and mentorship programs aimed at training new researchers were also mentioned.

Regarding investments and sponsors attraction, priorities included strategic partnerships (73 mentions), international promotion campaigns for Brazilian clinical research (67), tax benefits (54), and incentives for national industry (53). The main qualitative suggestions were the need for greater regulatory predictability, post-study incentives, and review of taxes on the importation of inputs.

Regarding decentralization and regionalization, the most frequently cited aspects were strengthening local infrastructure (79 mentions), forming collaborative networks (74), and regional capacity-building (59). Incentives for studies outside major centers and territorial funding mechanisms were also mentioned, pointing to the urgency of policies that promote territorial equity in clinical research.

In the field of information and transparency, participants highlighted the lack of integrated public platforms (65 mentions), low interoperability among the Brazilian Clinical Trials Registry (ReBEC), Plataforma Brasil, and the National Health Regulatory Agency (63), and insufficient dissemination of results (28).

Regarding the MoH's role, the priorities indicated were direct financial incentives (45 mentions), support for capacity-building and institutionalization of centers (44), data integration and use (43), and strengthening of national networks (41), reinforcing the importance of the Ministry's coordinated action in promoting regulatory efficiency and cooperation among institutions.

Table 2 summarizes the main lessons learned and recommendations derived from the consultation. The results highlight complex and fragmented regulation, concentrated infrastructure, low inclusion of underrepresented populations, and unstable financing as central challenges. The lessons learned point to the urgency of regulatory clarity, system interoperability, diversification of resources, and expansion of equity. The main practical recommendations were the publication of a regulatory decree for Law Nº 14.874/2024[12], the creation of regional hubs, simplification of workflows, implementation of inclusion programs, and the establishment of dedicated funds for clinical research.

Table 2. Comparative summary of results, lessons learned, and recommendations from Public Consultation SECTICS/MS Nº 69, Brazil, 2025

Results	Lessons learned	Recommendations
Complex regulatory framework, with unclear timelines and application regarding Law No. 14.874/2024.	Urgent need for greater regulatory clarity and flow predictability.	Issue implementing regulations, align requirements with international standards, and establish cleartimelines.
Indiscriminate application of the law to Humanities and Social Sciences research	Failure to distinguish non-clinical research areas creates unnecessary regulatory barriers.	Establish a specific framework for Humanities and Social Sciences and strengthen the national oversight body.
Research infrastructure concentrated in the South and Southeast regions; outdated "Plataforma Brasil" system.	Uneven distribution of infrastructure and limited interoperability among digital platforms.	Establishregional hubs, certify research centers, replace the 'Plataforma Brasil' system, and integrate national databases.
Excessive bureaucracy, centralized processes, and overlapping responsibilities among review bodies.	Excessive procedural steps undermineefficiency.	Streamline processes, establishpublic regulatory performance indicators, and increase the number of accredited Research Ethics Committees (RECs).
Predominance of Phase III studies and limited preclinical and Phase I/II research capacity	Underdevelopment of early-stage research limits innovation.	PromotePhase I/II centers and support preclinical and advanced therapy laboratories.
Limited inclusion of underrepresented populations and regional disparities.	Lack of equity, diversity, and inclusion (EDI).	Implement inclusion initiatives, increase the participation of underrepresented groups, and promote a more balanced regional distribution of research.
Unstable funding and heavy dependence on the pharmaceutical industry.	Limited and insufficiently diversified funding sources.	Introduce tax incentives, encourage mixed-capital funds, and establish dedicated funding streams for clinical research.
Limited use of evidence in public policy.	Research evidence is rarely translated into protocols and policy decisions.	Establish mechanisms for implementation research and ensure that research findings are published in accessible formats.

Source: Prepared by the authors.

Discussion

The analysis of contributions from SECTICS/MS Public Consultation Nº 69/2025 provides insight into Brazilian clinical research as a strategic field under consolidation, marked by institutional advances, but still constrained by persistent structural limitations. The findings point to an ecosystem with substantial scientific capacity and participation in advanced-phase clinical studies, while coexisting with challenges related to regulation, financing, human resources training, and regional inequality. This configuration suggests an arrangement typical of middle-income countries, characterized by uneven integration into global health innovation dynamics[13,14].

The concentration of activities in Phase II and III studies, combined with the strong presence of public and academic institutions, highlights the State's strategic role in conducting clinical research in the country. This pattern reinforces the central role of the SUS not only as a user of evidence, but also as a driver of scientific and technological agendas, particularly within the scope of the CEIS[15]. From this perspective, clinical research bridges healthcare delivery and productive

development, simultaneously contributing to improved care and technological development.

The concentration of research capacity in the Southeast and South reflects persistent regional asymmetries in the national science and technology system. This backdrop points to the need for strategies oriented toward decentralization that promote the strengthening of local capacities, the formation of collaborative networks, and the expansion of population diversity in clinical studies. The inclusion of different social and epidemiological contexts not only enhances the representativeness of the evidence, but also strengthens its applicability within the SUS[16].

As for the regulatory environment, the findings indicate the persistence of obstacles associated with institutional fragmentation and low predictability of processes, especially at the interface between ethical and health regulatory review. This situation has recurrently been pointed out as a limiting factor for Brazil's competitiveness in attracting and participating in international clinical studies[17]. The results suggest that advances in this field depend on coordination among regulatory bodies, adoption of risk-proportionate approaches, and strengthening of institutional capacities, in order to balance ethical protection and operational efficiency[13].

The perception of slowness and unpredictability in regulatory processes reinforces the need to move forward in consolidating more modern, efficient, and risk-proportionate guidelines. In this regard, the adoption of risk-based approaches becomes fundamental, allowing regulatory assessments to be prioritized according to potential health impact, as well as the implementation of reliance mechanisms, which enable regulatory authorities to leverage assessments conducted by reference regulatory authorities[18].

Furthermore, these findings emphasize the importance of integration and articulation among different regulatory and institutional bodies, promoting greater coordination, transparency, and predictability in decision-making flows. These aspects have been widely debated and recommended by international organizations, such as the World Health Organization (WHO) and the European Medicines Agency (EMA)[19,21], in the context of strengthening more agile and robust regulatory systems aligned with global best practices.

Financial sustainability constitutes another critical dimension. The participants' emphasis on diversified funding sources highlights the insufficiency of models based predominantly on public financing. In the Brazilian context, although research financing has historically been supported by public agencies – such as the National Council for Scientific and Technological Development (CNPq), the Coordination for the Improvement of Higher Education Personnel (CAPES), and state research support foundations – there is a need to expand and articulate other sources of funding.

In this regard, private-sector funding emerges as a relevant alternative, both through industry-sponsored studies and through initiatives conducted by researchers or in public-private collaborative arrangements. Moreover, the national ecosystem has incorporated innovative funding mechanisms, such as crowdfunding platforms and institutional philanthropic initiatives. At the international level, major international funding agencies and foundations also provide important opportunities, expanding the possibilities for sustaining strategic projects[22]. This set of alternatives reinforces the importance of an integrated and diversified financing strategy to ensure greater stability, predictability, and scalability for research activities.

The literature on the CEIS highlights that the sustainability of clinical research depends on hybrid instruments that combine public resources, private capital, and international cooperation[15,23]. In this regard, arrangements that integrate state investment, private capital, and international cooperation gain relevance, especially in the context of the CEIS, in which articulation between innovation and health production is strategic for national

development[24]. Furthermore, we underscore the importance of financing mechanisms directed toward early stages of development and translational research, as they constitute a strategic link between basic science and therapeutic innovation[25].

Workforce development emerged as a cross-cutting dimension across the challenges identified. The demand for structured training, certifications, and continuous capacity-building programs reflects the centrality of a skilled workforce for conducting increasingly complex clinical studies and integrating the country into international research networks, being directly related to technology absorption capacity and scientific sovereignty. In Brazil, where much clinical research is conducted in academic settings and teaching hospitals, frequently linked to public universities, these challenges are intensified, given the overlapping care, education, research, and management activities.

In this context, we highlight constraints related to protected research time and the availability of qualified professionals to support research activities. Overcoming these barriers requires training, strengthening infrastructure, providing more equitable distribution of resources, ensuring protected time for research, and defining strategic agendas, essential elements for consolidating sustainable capacities[26,27].

In the field of real-world studies, we highlight the need for greater integration among information systems. Fragmented digital platforms and limited interoperability compromise process transparency, traceability, and efficiency[28,29]. These findings reveal challenges in aligning current practices with contemporary open science and health data management principles, indicating the importance of solutions that facilitate integration and secure sharing of information. In this context, the literature on open science and data governance highlights interoperability and active dissemination of results as pillars of public trust and institutional efficiency[30].

From the perspective of public policies, the results reinforce the need for integrated approaches that integrate regulation, funding, workforce development, infrastructure, and governance. In the context of the SUS, this articulation is fundamental to ensuring that knowledge production is oriented toward the needs of the population and reduces health inequalities. Thus, clinical research must be understood as a strategic component of innovation policies and of strengthening the CEIS, in direct alignment with the principles of the PNCTIS[31].

The incorporation of emerging technologies, such as artificial intelligence, big data, and precision health approaches, points to the country's alignment with global trends in the transformation of clinical research[32,33]. However, these advances also introduce new challenges, especially in the regulatory and ethical fields, requiring more adaptive regulatory frameworks and institutional capacity to address increasing technological complexity[34,35].

It is important to recognize the limitations of this consultation. First, the sample was geographically imbalanced, which stems from the predominance of participants from the Southeast and South regions. Second, the consultation relied on self-reported perceptions collected through a self-administered questionnaire, whose results reflect respondents' opinions and experiences but do not objectively measure performance indicators.

In addition, participant self-selection may have disproportionately represented the views of stakeholders who were more engaged or more familiar with regulatory and funding mechanisms. In this regard, an important limitation was the absence of variables that would allow more precise characterization of respondents' level of experience or knowledge regarding the clinical research regulatory framework or their previous involvement in ethical review processes, which restricts the performance of more in-depth stratified analyses. Finally, the cross-sectional and descriptive nature of the consultation does not allow causal inference or longitudinal assessment of the

potential effects of recent institutional changes, such as the regulation of Law Nº 14,874/2024[12].

Despite these limitations, the study has important strengths. The diversity of profiles and sectors represented allowed us to capture the multiple perspectives underpinning the field of clinical research. The thematic breadth of the questions contributed to a systemic analysis that integrates ethical, regulatory, financial, training-related, and technological dimensions. Furthermore, the consultation was conducted in a context marked by regulatory reforms and by a movement to review and update the Action Plan for Clinical Research in Brazil. This context enhances the strategic relevance of the findings and their potential to inform governmental guidelines and actions.

In summary, the findings indicate that strengthening clinical research in Brazil depends on structural transformations that address regulatory fragmentation, regional inequality, financing instability, and human resources training gaps. The consolidation of a more robust and equitable ecosystem requires coordinated action among the State, the productive sector, and the scientific community, guided by principles of equity, transparency, and scientific sovereignty, and aligned with the SUS objectives.

Authorship contributions

França GVA (0000-0002-7530-2017)* contributed to the conception and design of the study, definition of the methodological design, analytical planning, organization and distribution of tasks among the authors, data collection, processing and statistical analysis, interpretation of results, drafting of the initial version, critical review of the intellectual content, and approval of the final version of the manuscript. Lupatini EO (0000-0001-6231-891X)*, Sfalsini RBT (0009-0000-6683-9413)*, Pereira MZ (0009-0007-3747-9376)*, Ribeiro AL (0000-0003-4917-4469)*, Waldrich KAM (0009-0006-4162-0865)*, and Pureza JC (0009-0003-7169-7984)* contributed to the conception and design of the study, definition of the methodological design, data collection and processing, interpretation of results, critical review of the intellectual content, and approval of the final version of the manuscript. Freitas MS (0009-0001-5788-5917)* and De Negri F (0000-0002-3197-5156)* contributed to the conception and design of the study, definition of the methodological design, interpretation of results, critical review of the intellectual content, and approval of the final version of the manuscript. ■

References

1. Kandi V, Vadakedath S. Clinical Research: An Overview of Study Types, Designs, and Their Implications in the Public Health Perspective. Am J Clin Med Res. 2021;9(2):36-42. DOI: https://doi.org/10.12691/ajcmr-9-2-1

2. Tenório M, Mello GA, Viana ALDÁ. Políticas de fomento à ciência, tecnologia e inovação em saúde no Brasil e o lugar da pesquisa clínica. Ciênc saúde coletiva. 2017;22(5):1441-54. DOI: https://doi.org/10.1590/1413-81232017225.33342016

3. Dainesi SM, Goldbaum M. Pesquisa clínica como estratégia de desenvolvimento em saúde. Rev Assoc Med Bras. 2012;58(1):2-6. DOI: https://doi.org/10.1590/S0104-42302012000100002

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4. Oliveira RR, Viana ALÁ. Expansão global dos ensaios clínicos: inovação e interação. Cad Saúde Pública. 2019;35(11):e00063518. DOI: https://doi.org/10.1590/0102-311X00063518

5. Presidência da República (BR). Decreto nº 11.798, de 28 de novembro de 2023. Aprova a Estrutura Regimental e o Quadro Demonstrativo dos Cargos em Comissão e das Funções de Confiança do Ministério da Saúde e remaneja e transforma cargos em comissão e funções de confiança. Diário Oficial da União, Brasília, DF. 2023 nov 28; Edição 255-B; Seção I:1.

6. Ministério da Saúde (MS), Gabinete do Ministro. Portaria 559, de 9 de março de 2018. Altera a Portaria de Consolidação nº 5/GM/MS, de 28 de setembro de 2017, para instituir o Plano de Ação de Pesquisa Clínica no Brasil. Brasília, DF. 2018 mar 14; Edição 50; Seção I:53.

7. Ministério da Saúde (BR), Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde, Departamento de Ciência e Tecnologia. Plano de ação de pesquisa clínica no Brasil. Brasília, DF: Ministério da Saúde; 2020. 47 p.

8. Ministério da Saúde (BR), Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde, Departamento de Ciência e Tecnologia. Política nacional de ciência, tecnologia e inovação em saúde. 2ª ed. Brasília, DF: Editora do Ministério da Saúde; 2008. 44 p.

9. Bardin L. Análise de conteúdo. Lisboa: Edições 70; 1977.

10. Ministério da Saúde (BR), Conselho Nacional de Saúde. Resolução nº 674, de 6 de maio de 2022. Dispõe sobre a tipificação da pesquisa e a tramitação dos protocolos de pesquisa no Sistema CEP/Conep. Diário Oficial da União, Brasília, DF. 2022 out 25; Edição 203; Seção I:65.

11. Presidência da República (BR). Lei nº 13.709. Lei Geral de Proteção de Dados Pessoais (LGPD). Diário Oficial da União, Brasília, DF. 2018 ago 14; Edição 157; Seção I:59.

12. Presidência da República (BR). Lei nº 14.874, de 28 de maio de 2024. Dispõe sobre a pesquisa com seres humanos e institui o Sistema Nacional de Ética em Pesquisa com Seres Humanos. Diário Oficial da União, Brasília, DF. 2024 maio 29; Edição 103; Seção I:3.

13. Resende H, Rebelatto TF, Werutsky G, et al. Current scenario and future perspectives of clinical research in Brazil: a national survey. Ecancermedicalscience. 2023;17:1640. DOI: https://doi.org/10.3332/ecancer.2023.1640

14. Gossling G, Rebelatto TF, Villarreal-Garza C, et al. Current Scenario of Clinical Cancer Research in Latin America and the Caribbean. Curr Oncol. 2023;30(1):653-62. DOI: https://doi.org/10.3390/curroncol30010050

15. Gadelha CAG, Temporão JG. Desenvolvimento, Inovação e Saúde: a perspectiva teórica e política do Complexo Econômico-Industrial da Saúde. Ciênc saúde coletiva. 2018;23(6):1891-902. DOI: https://doi.org/10.1590/1413-81232018236.06482018

16. Zago MA. A pesquisa clínica no Brasil. Ciênc saúde coletiva. 2004;9(2):363-74. DOI: https://doi.org/10.1590/S1413-81232004000200013

17. David AC, Lima JPR. Estudo comparativo dos prazos regulamentares da pesquisa clínica de medicamento do Brasil, Estados Unidos da América, Argentina e França. Revista Pensamento & Realidade. 2018;33(3):90-109. DOI: https://doi.org/10.23925/2237-4418.2018v33i3p90-109

18. van-der-Zee IT, Vreman RA, Liberti L, et al. Regulatory reliance pathways during health emergencies: enabling timely authorizations for COVID-19 vaccines in Latin America. Rev Panam Salud Publica. 2022;46:e115. DOI: https://doi.org/10.26633/RPSP.2022.115

19. Zinken JF, Pasmooij AMG, Ederveen AGH, et al. Environmental risk assessment in the EU regulation of medicines for human use: an analysis of stakeholder perspectives on its current and future role. Drug Discov Today. 2024;29(12):104213. DOI: https://doi.org/10.1016/j.drudis.2024.104213

20. Scheppler L, De Clercq N, McGoldrick M, et al. Regulatory harmonization and streamlining of clinical trial applications globally should lead to faster clinical development and earlier access to life-saving vaccines. Vaccine. 2021;39(5):790-6. DOI: https://doi.org/10.1016/j.vaccine.2020.11.077

21. World Health Organization. Guidance for best practices for clinical trials. Geneva: WHO; 2024. 76 p.

22. Gomes CM, Marchini G, Júnior JB, et al. The landscape of biomedical research funding in Brazil: a current overview. Int Braz J Urol. 2024;50(2):209-22. DOI: https://doi.org/10.1590/s1677-5538.ibju.2024.9905

23. Barreto AAM, Mendes SJ, Mendes ÁN. O pensamento desenvolvimentista na raiz do Complexo Econômico-Industrial da Saúde (Ceis): uma revisão integrativa. Saúde Debate. 2025;49(145):e9855. DOI: https://doi.org/10.1590/2358-289820251459855P

24. Oliveira GRR, Silva ALG. O conceito do complexo econômico-industrial da saúde na prática: um olhar sobre o caso das parcerias para o desenvolvimento produtivo. Econ Soc. 2022;31(3):627-50. DOI: https://doi.org/10.1590/1982-3533.2022v31n3art04

25. Gadelha CAG, Vargas MA, Alves NG. Pesquisa translacional e sistemas de inovação na saúde: implicações para o segmento biofarmacêutico. Saúde Debate. 2019;43(Esp 2):133-46. DOI: https://doi.org/10.1590/0103-11042019S210

26. Laurila KA, Sanderson K, Lane TS, et al. Building capacity for health research in higher education: Evaluating readiness for research and scholarship. Eval Program Plann. 2025;113:102672. DOI: https://doi.org/10.1016/j.evalprogplan.2025.102672

27. Tulloch-Reid MK, Saravia NG, Dennis RJ, et al. Strengthening institutional capacity for equitable health research: lessons from Latin America and the Caribbean. BMJ. 2018;362:k2456. DOI: https://doi.org/10.1136/bmj.k2456

28. Costa MVS, Camargos MCS, Viana SMN, et al. Avanços e desafios da interoperabilidade no Sistema Único de Saúde. J Health Inform. 2025;17(1):1112. DOI: https://doi.org/10.59681/2175-4411.v17.2025.1112

29. Rivabem FS, Faleiros Júnior JLM. Transformação digital no sistema Único de Saúde: interoperabilidade, governança e proteção de dados sensíveis. Rev Dir Sanit. 2025;25(1):1-14. DOI: https://doi.org/10.11606/issn.2316-9044.rdisan.2025.231455

30. Gonçalo W, Souza MC, Santos WP, Oliveira FHC. Abordagens regulatórias na proteção de dados em saúde: uma revisão integrativa de 2018 a 2023. Physis. 2025;35(1):e350113. DOI: https://doi.org/10.1590/S0103--73312025350113pt

31. Guimarães R, Teixeira MO. Ciência e Tecnologia e Inovação em Saúde no Brasil: reflexões e prioridades. Physis. 2025;35(1):e350121. DOI: https://doi.org/10.1590/S0103-73312025350113pt

32. Ng CE, Bowman S, Ling J, et al. The future of clinical trials-is it virtual? Br Med Bull. 2023;148(1):42-57. DOI: https://doi.org/10.1093/bmb/ldad022

33. Feero WG. Introducing "Genomics and Precision Health". JAMA. 2017;317(18):1842-3. DOI: https://doi.org/10.1001/jama.2016.20625

34. Mennella C, Maniscalco U, De Pietro G, et al. Ethical and regulatory challenges of AI technologies in healthcare: A narrative review. Heliyon. 2024;10(4):e26297. DOI: https://doi.org/10.1016/j.heliyon.2024.e26297

35. Stenzinger A, Moltzen EK, Winkler E, et al. Implementation of precision medicine in healthcare-A European perspective. J Intern Med. 2023;294(4):437-54. DOI: https://doi.org/10.1111/joim.13698

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