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Corporate Governance and Bioethics of Biomedical Capital Formation in Latin America

Gilberto Bermúdez Ruiz, Leticia María González Velásquez, Tirso Javier Hernández Gracia, Reyna Amador Velázquez, Nadya Elizabeth Vásquez Segura, Juan Guillermo Mansilla Sepulveda, Jorge E. Chaparro Medina, Isabel Cristina Rincón Rodríguez, Alfredo Barrera Escolar, Sonia Sujell Vélez Báez

(Corresponding Author), Universidad Anáhuac, Campus México, gibe_gil@hotmail.com
Universidad de Sonora (USON), lmgv@uson.mx
Universidad Autónoma del Estado de Hidalgo (UAEH), thernan@uaeh.edu.mx
Universidad Autónoma del Estado de México (UAEMEX), ramadorv@uaemex.mx
ICEEM, nevs@iceem.mx
Universidad de La Frontera–Temuco (UTEMUCO), jmansilla@utemuco.cl
Universidad de Investigación y Desarrollo (UDI), jecm@udi.co
Universidad de Investigación y Desarrollo (UDI), icrr@udi.co
Universidad Francisco de Vitoria (UFV), abe@ufv.mx
Universidad Autónoma de Querétaro (UAQ), sujallvb@uaq.mx

ABSTRACT

The formation of biomedical capital in Latin America has become central to contemporary health innovation, investment strategies and the regional consolidation of corporate governance structures that regulate clinical data, biobanking, pharmaceutical development and the circulation of knowledge derived from human biological materials. In this context, bioethics functions not only as a normative safeguard but also as a framework through which legitimacy, transparency and distributive justice can be evaluated in relation to public and private biomedical ventures. This study analyzes how corporate governance mechanisms intersect with bioethical principles in shaping biomedical capital formation across Mexico, Colombia, Chile and Argentina. A mixed-methods design was implemented, combining documentary analysis of regulatory frameworks, statistical data on R&D investment and qualitative interviews with 36 key informants, including researchers, policymakers and private-sector actors. Results reveal persistent asymmetries in regulatory enforcement, weak alignment between governance standards and bioethical safeguards, and emerging conflicts involving data ownership, consent models, and commercial uses of genomic information. Quantitative findings from three comparative tables show increasing private-sector dominance in biomedical patenting, limited public oversight and significant gaps in ethical review capacity. Interview excerpts complement these results by illustrating tensions between innovation incentives and respect for autonomy, community benefit and equity. The discussion interprets these findings in the context of global health capital markets and Latin America's structural vulnerabilities. The study concludes by proposing a regional governance-bioethics integration model emphasizing transparency, cross-border regulatory harmonization and participatory mechanisms for biomedical decision-making

KEYWORDS: biomedical capital, corporate governance, bioethics, Latin America, genomic data, biotechnology governance, research ethics, biobanking

INTRODUCTION

The main objective of this study is to analyze how corporate governance mechanisms intersect with bioethical principles to shape the formation, regulation and distribution of biomedical capital in Latin America, with emphasis on Mexico, Colombia, Chile and Argentina. The study seeks to identify structural tensions between innovation-driven governance frameworks and ethically grounded oversight systems, assessing how these tensions influence genomic data management, biobanking practices, clinical research processes and biotechnology commercialization across the region (Rose, 2013; Ugalde & Homedes, 2021).

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The notion of biomedical capital has gained prominence as countries increasingly rely on biotechnology, pharmaceutical innovation and population-based genomic resources to shape public health strategies and economic development (Rose, 2013; Sunder Rajan, 2017). In Latin America, this trend has intensified due to structural reforms, the expansion of private research infrastructures and the growing participation of transnational corporations in genomic initiatives, biobanking and clinical trials (Lemus-Martínez & Pérez-Reyna, 2022). Scholars have noted that these transformations unfold within fragile governance systems marked by heterogeneous regulations, insufficient institutional capacity and persistent socioeconomic inequalities (Río-Salgado & Peña-López, 2021). Consequently, the formation of biomedical capital frequently advances more rapidly than the accompanying ethical and regulatory safeguards.

Corporate governance frameworks influence how institutions manage transparency, accountability, conflict of interest, intellectual-property rights and stakeholder participation. In the biomedical sector, governance structures also determine access to biological samples, control of genomic information and mechanisms for public oversight (Cannavò & Palumbo, 2020). In Latin America, these frameworks are shaped by hybrid arrangements where imported standards intersect with domestic constraints, often generating discrepancies between formal regulations and actual practices (Ugalde & Homedes, 2021). Bioethics plays a central role in mediating these gaps, providing principles that guide decision-making where human biological materials are collected, stored or commercialized. However, several authors document that ethical review boards in the region face challenges such as inadequate funding, limited autonomy and inconsistent methodological rigor (Petrini et al., 2020).

The rapid expansion of genomic platforms illustrates these tensions. Mexico, Colombia and Chile have invested in national genomic initiatives and partnered with private laboratories to collect large-scale population data (Camacho-Sánchez & Moreno-López, 2023). Despite the potential scientific benefits, studies emphasize that regional policies remain insufficient to guarantee fair benefit-sharing, culturally appropriate consent and long-term data protection (González-Pérez & Luna-Martínez, 2019). Corporate governance models often prioritize efficiency and innovation, while bioethical frameworks emphasize justice, autonomy and social responsibility; thus, a normative tension emerges between commercial expectations and ethical obligations (Hedgecoe, 2022).

This article analyzes how these tensions manifest in four countries—Mexico, Colombia, Chile and Argentina—selected for their distinct regulatory arrangements and growing biomedical industries. The mixed-methods approach employed integrates quantitative indicators of R&D investment and patent activity with qualitative accounts from 36 key informants involved in research governance, bioethics oversight and biotechnology innovation. This perspective builds on current debates highlighting the need for governance models that integrate ethical and social considerations into the management of biomedical resources (Jasanoff & Hurlbut, 2018). By examining how governance and bioethics interact, the study aims to clarify how biomedical capital is produced, who benefits from its expansion and which ethical tensions require urgent regional attention.

The expansion of biomedical capital in Latin America has occurred within governance systems characterized by regulatory fragmentation, uneven institutional capacities and limited public oversight (Ribeiro & Santos, 2020). As biotechnology industries increasingly rely on genomic databases, clinical trial outsourcing and public–private collaborations, ethical concerns regarding informed consent, data ownership, equitable benefit-sharing and community representation have intensified (Hedgecoe, 2022). Corporate governance structures in biotechnology and pharmaceutical sectors emphasize competitiveness, intellectual-property protection and investment efficiency, yet these priorities often conflict with bioethical principles such as autonomy, justice and transparency (Cannavò & Palumbo, 2020). Consequently, the formation of biomedical capital unfolds through processes that may reinforce existing inequalities, weaken participant protections and constrain democratic participation in decision-making. The problem addressed in this study is the persistent misalignment between corporate governance mechanisms and bioethical oversight in the development of biomedical capital in Latin America, and the implications of this misalignment for scientific legitimacy, social

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justice and public trust.

How do corporate governance mechanisms intersect with bioethical principles to shape biomedical capital formation in Mexico, Colombia, Chile and Argentina, and what structural tensions emerge from this interaction in relation to genomic data management, clinical research oversight and biotechnology commercialization?

Hypothesis 1. Countries with stronger corporate governance transparency indicators will show more consistent implementation of bioethical safeguards in genomic data management and clinical research oversight (Petrini et al., 2020).

Hypothesis 2. Higher levels of private-sector investment in biomedical research will correlate with greater tensions between innovation incentives and the protection of participant autonomy and data rights (Sunder Rajan, 2017).

Hypothesis 3. Weak regulatory harmonization across Latin America will be associated with increased disparities in ethical review processes, benefit-sharing agreements and public accountability mechanisms (Jasanoff & Hurlbut, 2018).

METHOD

The study adopted a mixed-methods design integrating quantitative and qualitative strategies to examine how corporate governance mechanisms interact with bioethical principles in the formation of biomedical capital in Latin America. Mixed-methods approaches are especially appropriate for analyzing complex health-governance environments because they combine numerical indicators with contextualized perspectives from institutional actors, thus enabling a more comprehensive understanding of regulatory tensions, ethical dilemmas and investment structures (Creswell & Plano Clark, 2018). This design was selected to capture variations in national regulatory frameworks, private investment patterns and ethical-review practices while also incorporating experiential accounts from experts who participate directly in decision-making processes. The quantitative component focused on R&D investment trends, patent registrations and national indicators of regulatory capacity. The qualitative component included semi-structured interviews aimed at exploring perceptions of ethical oversight, conflicts of interest, data-governance challenges and the sociopolitical contexts in which biomedical capital is produced.

Design

The research followed an explanatory sequential mixed-methods design in which quantitative analysis informed the selection of qualitative informants and guided the thematic depth of interviews (Fetters et al., 2013). The initial phase consisted of collecting public data from national science and technology agencies, regional patent offices, biobank registries and health-research regulatory bodies in Mexico, Colombia, Chile and Argentina. The second phase employed qualitative interviews to contextualize statistical trends and uncover governance-bioethics tensions that numerical indicators alone could not capture. This design ensured methodological triangulation, increasing the validity of findings by comparing multiple data sources and analytic procedures (Tashakkori & Teddlie, 2020). The integration of both components occurred during the interpretation stage, where qualitative excerpts were linked to quantitative patterns to explain divergences across countries.

Sample

The quantitative sample consisted of national-level datasets published between 2018 and 2024 by the Consejo Nacional de Humanidades, Ciencias y Tecnologías (CONAHCYT) in Mexico, the Ministerio de Ciencia, Tecnología e Innovación in Colombia, the Agencia Nacional de Investigación y Desarrollo (ANID) in Chile and the Ministerio de Ciencia, Tecnología e Innovación Productiva in Argentina. Patent data were extracted from the regional database of the Observatorio de Ciencia, Tecnología e Innovación. These datasets were selected because they represent official, comparable and standardized indicators of scientific investment and

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regulatory activity, allowing for cross-national analyses consistent with previous studies in global health governance (Kickbusch et al., 2021).

The qualitative sample consisted of 36 key informants selected through purposive and criterion sampling. Purposive sampling ensured that participants held expertise relevant to corporate governance, research ethics, biotechnology policy or biomedical innovation (Patton, 2015). Criterion sampling ensured that participants had at least five years of experience in research oversight, ethical review, regulatory enforcement or participation in biomedical innovation networks. The final sample included 10 bioethics committee members, 8 biomedical researchers, 7 biotechnology-industry executives, 6 health-policy regulators and 5 directors of academic research units. This composition made it possible to incorporate perspectives from sectors involved in the governance of biological samples, genomic data and clinical research.

Instruments

Quantitative instruments consisted of structured extraction matrices designed to collect standardized indicators of R&D expenditure, public and private investment, patent registrations, and regulatory compliance metrics. These matrices were derived from OECD methodology for science and technology indicators, ensuring validity for cross-country comparisons (OECD, 2022). Each matrix included categories for year, investment modality, regulatory action type and patent classification under the International Patent Classification system. Reliability was ensured through double coding by two independent researchers with an inter-coder agreement of 0.92.

The qualitative instrument was a semi-structured interview guide developed according to best practices in research ethics and governance studies (Kvale & Brinkmann, 2015). The guide included questions on perceptions of regulatory enforcement, conflicts of interest in biotechnology investment, data-governance challenges, community engagement, and experiences with informed-consent models in genomic and clinical research. Probing questions were included to elicit detailed narratives regarding tensions between innovation incentives and bioethical obligations. The guide underwent expert validation by three senior bioethicists and two specialists in science-and-technology policy, resulting in adjustments that improved clarity and thematic depth.

Procedure

Quantitative data collection occurred between January and June 2024. Official statistical repositories were accessed and records were filtered to include only those relevant to R&D indicators, patenting activities and regulatory actions in biomedical research. Data were systematized in a comparative database, normalized per million inhabitants to allow demographic comparability and structured according to OECD science and technology categories. Qualitative data collection occurred between July and November 2024. Participants were contacted via institutional emails and invited to participate voluntarily. All interviews were conducted virtually, lasted between 45 and 70 minutes and were recorded with participants' informed consent. Ethical approval was granted by the research ethics committee at Universidad Anáhuac, following international guidelines for research involving human informants (CIOMS, 2016). Recordings were transcribed verbatim and anonymized to protect participants' identities.

The integration of quantitative and qualitative components followed a multilevel triangulation procedure. First, descriptive and inferential patterns in the quantitative dataset were reviewed to identify countries with contrasting regulatory or investment behaviors. These contrasts informed the prioritization of qualitative themes. Second, interview excerpts were linked with quantitative indicators to support or challenge emerging explanations. Third, thematic matrices were constructed to align governance variables with ethical concerns identified in the literature, enhancing coherence across sources (Nowell et al., 2017).

Analysis

Quantitative analysis included descriptive statistics, cross-national comparisons and correlation tests to examine relationships between governance indicators, investment levels and ethical-review capacity. These

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analyses followed established procedures in comparative science-policy research, allowing for the identification of statistically meaningful patterns in regulatory activity and R&D dynamics (Coccia, 2020). All quantitative procedures were conducted using SPSS v.28.

Qualitative data were analyzed using thematic analysis, following Braun and Clarke's (2021) six-phase framework: familiarization with data, coding, theme generation, theme review, theme definition and reporting. Codes were developed inductively and deductively, incorporating categories derived from governance theory, bioethical principles and empirical narratives. Reliability was strengthened through double coding and consensus meetings between researchers. Integration of quantitative and qualitative results occurred through joint display tables, allowing for meta-inference generation aligned with mixed-methods literature (Creswell & Plano Clark, 2018).

RESULTS

The combined quantitative and qualitative evidence indicates a marked heterogeneity in how biomedical capital is formed, governed and ethically overseen across Mexico, Colombia, Chile and Argentina. Table 1 summarizes public and private investment flows, patent intensity and the relative share of foreign-sponsored clinical trials for the period analyzed. Interpretation of Table 1 shows that Mexico and Colombia exhibit a pattern of heavy reliance on foreign-sponsored clinical research and larger private investment compared with public R&D funding, whereas Chile and Argentina demonstrate higher biotechnology patenting per million inhabitants and a lower proportion of foreign-sponsored clinical trials. These patterns suggest two contrasting routes to biomedical capital: one based on service provision to external sponsors and clinical trial hosting, and another emphasizing domestic innovation and patenting. An informant from Mexico, a chair of an institutional ethics committee, described this situation as follows: "The pace of clinical trials is fast, especially those funded abroad. Oversight has not grown at the same speed, which leaves important gray areas." This extract directly relates to the numbers in Table 1, reinforcing the interpretation that high foreign-sponsored trial shares coincide with governance pressures and oversight gaps reported by local actors.

Table 1. Comparative Indicators of Biomedical Capital Formation (2018–2024)

Country	Public R&D Investment in Health (USD millions)	Private Investment (USD millions)	Biotechnology Patents per Million Inhabitants	Foreign-Sponsored Clinical Trials (%)
Mexico	1,240	2,310	18	72
Colombia	680	1,150	11	69
Chile	910	1,480	36	54
Argentina	1,020	1,260	41	48

A second cluster of findings concerns the state of regulatory oversight, the presence of biobanks and the implementation of digital monitoring systems. Table 2 presents indicators of annual regulatory actions, registered biobanks, presence of digital monitoring systems, and average time for regulatory response. Interpreting Table 2 together with qualitative data reveals that countries with more frequent regulatory actions and implemented digital monitoring report faster response times and stronger sample/data traceability, which in turn enables more robust enforcement of ethical and governance standards. For example, the Argentine research director emphasized operational advantages associated with digital capacity: "Having digital systems for tracking samples and data has improved our ability to act quickly. Before, coordinating a response took much longer." This comment aligns with the data in Table 2 showing Argentina and Chile with full digital monitoring systems and comparatively shorter average regulatory response times. Conversely, the informant from Colombia summarized the limitations faced where digital infrastructure is incomplete: "We do perform audits, but our digital infrastructure is limited. Many follow-up processes are still manual, and that reduces our ability to ensure transparency." Such qualitative testimony helps to explain why the lower number of regulatory actions or partial digital monitoring in Mexico and Colombia may not only reflect institutional will but also technical constraints that hinder oversight effectiveness.

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Table 2. Regulatory Oversight Indicators in Biomedical Research (2020–2024)

Country	Annual Regulatory Actions (Audits, Sanctions, Reviews)	Registered Biobanks	Digital Monitoring Systems Implemented	Average Time for Regulatory Response (days)
Mexico	342	18	Partial	57
Colombia	201	12	Partial	63
Chile	418	22	Full	39
Argentina	390	20	Full	41

A third set of results centers on the capacity, autonomy and training of research ethics committees, shown in Table 3. The table indicates differences in the number of active committees, average approval times, the percentage operating with high autonomy and annual training hours per member. Interpretation of these data together with informant extracts highlights that higher autonomy and greater training correlate with shorter approval times and with stakeholders' perceptions of more credible ethical oversight. In Chile and Argentina the proportion of committees operating with high autonomy and the higher training hours per member coincide with lower approval times, which interviewees associated with institutional investment in capacity building and independence from sponsor influence. A Chilean regulator noted, "Investment has increased, but we built regulatory channels earlier. This has allowed us to integrate patents, genomic projects and clinical research under a more coherent governance structure." Similarly, a Chilean bioethicist said, "The higher autonomy here is the result of long-term institutional investment. Committees can make decisions without pressure from sponsors or administrators." In contrast, Mexican interviewees emphasized variability and dependency on institutional hierarchies: "Our autonomy depends on the institution. Some committees have strong independence, but others operate under administrative constraints that influence decisions." These qualitative statements help to interpret Table 3 by connecting numerical autonomy indicators with perceived independence and real constraints on ethical decision-making across institutions.

Table 3. Ethics Committee Capacity and Autonomy Indicators (2021–2024)

Country	Active Research Ethics Committees	Average Approval Time (days)	Percentage Operating with High Autonomy	Training Hours per Member (Annual)
Mexico	146	52	43%	18
Colombia	103	57	38%	15
Chile	128	33	67%	27
Argentina	134	29	71%	24

Bringing these strands together, the integrated interpretation indicates that biomedical capital formation in the region is shaped by an interplay of investment patterns, technological capacity for oversight and the institutional strength of ethical review mechanisms. Countries that show higher domestic patenting intensity (Chile and Argentina, Table 1) and that have invested earlier in digital monitoring systems and ethics committee capacity (Tables 2 and 3) tend to present governance configurations that better align bioethical safeguards with commercial and scientific objectives. Conversely, countries with higher shares of foreign-sponsored clinical trials and comparatively weaker digital oversight or ethics-committee autonomy (Mexico and Colombia, Tables 1–3) face pronounced tensions whereby rapid capital inflows and external sponsors create pressures that institutional governance and bioethical frameworks struggle to mediate. Informant testimony consistently illustrated these dynamics: stakeholders in hosting countries reported operational strain when sponsors' timelines and commercial priorities collided with ethical review processes and community-engagement expectations. One Mexican ethics board member captured the dilemma succinctly: "Sponsors expect fast approvals and flexible consent arrangements; committees try to safeguard participants, but there is pressure to accommodate timelines."

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Finally, qualitative excerpts reveal recurring thematic concerns that complement and deepen the numerical findings. Across the four countries informants raised issues concerning consent models for genomic data, clarity of data ownership and benefit-sharing arrangements, and the influence of private funding on institutional agendas. These concerns help interpret why numbers alone—such as patent counts or investment totals—do not fully capture ethical risk: the governance capacity to translate formal rules into practice, the presence of digital traceability tools and the independence and training of ethics committees are decisive mediating factors. In sum, the results show that while biomedical capital is increasing across the region, its ethical embedding and governance legitimacy vary substantially; the combination of the three tables and the informant extracts makes clear that structural investments in oversight and capacity are associated with more coherent governance-bioethics configurations, whereas reliance on external trial sponsorship and limited institutional autonomy tend to exacerbate ethical vulnerabilities.

DISCUSSION

The results of this study reveal a fragmented but evolving landscape of biomedical capital formation in Latin America, where governance structures, ethical oversight mechanisms and investment flows interact in uneven ways across countries. These findings align with the broader literature suggesting that regions with heterogeneous political economies tend to generate equally heterogeneous biomedical innovation systems marked by uneven regulatory capacity, variable market incentives and inconsistent ethical safeguards (Petrinović, 2021). The contrast observed between Chile and Argentina—characterized by higher domestic patenting, more frequent regulatory actions and fully implemented digital monitoring—and Mexico and Colombia, which rely more heavily on foreign-sponsored clinical trials, reflects the structural asymmetries long documented in Latin American science and technology systems (Dagnino, 2019). Such asymmetries shape not only the speed of capital accumulation but also the ethical conditions under which biomedical knowledge is produced.

The patterns identified in Table 1 substantiate earlier arguments that foreign-sponsored clinical trials often introduce governance pressures that exceed local regulatory capacity, particularly when external sponsors impose accelerated timelines and complex contractual structures (Hoeyer, 2023). The qualitative extracts from Mexican and Colombian informants reinforce this dynamic, noting gaps in oversight and limited institutional capacity to match the pace of externally funded research. These observations resonate with analyses showing that the globalization of clinical trial markets frequently shifts ethical burdens to middle-income countries, where institutional infrastructures may not expand proportionally with research volume (Petryna, 2009). In contrast, the greater domestic patent activity in Chile and Argentina aligns with research demonstrating that stronger national innovation ecosystems, supported by sustained public investment, often correlate with more robust internal governance and higher bioethical coherence (Vasen & Luján, 2017).

The regulatory indicators presented in Table 2 reveal another dimension of regional divergence: the differential adoption of digital monitoring systems. Digital traceability—such as real-time tracking of samples, data flows and consent processes—has been recognized as a key governance tool for reducing ethical risk, minimizing data misuse and increasing institutional responsiveness (Rothstein et al., 2021). Countries with fully implemented digital infrastructure displayed faster regulatory response times, which is consistent with empirical studies showing that digitalization strengthens transparency and accountability in biomedical research, especially in contexts with historically uneven regulatory enforcement (Ribeiro & Shankland, 2020). The experiences described by Chilean and Argentine informants illustrate how digital capability enhances decision-making, reduces bureaucratic delays and allows committees to detect irregularities earlier in the research cycle.

Ethics committee performance, described in Table 3, offers a crucial link between capital formation and bioethics. Literature on research governance emphasizes that committee autonomy, professionalization and continuous training are essential for safeguarding participant welfare in environments with high commercial influence (Klugman, 2022). The shorter approval times in Chile and Argentina should not be interpreted as evidence of lax review; rather, they mirror findings that well-trained, independent committees are able to

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conduct efficient yet rigorous evaluations (Borry et al., 2015). Conversely, the lower autonomy and fewer annual training hours reported in Mexico and Colombia correspond to persistent concerns in the literature about institutional dependency, administrative pressure and variable committee standards in Latin American universities and hospitals (Homedes & Ugalde, 2016). The informant accounts from these countries provide qualitative confirmation of these structural constraints.

Across all four countries, qualitative data highlighted recurring ethical tensions related to genomic data governance, benefit-sharing arrangements and consent models. These issues reflect broader debates in global bioethics regarding the need to integrate equity, community involvement and participant rights into biomedical innovation systems (Tuckson et al., 2017). Several informants emphasized that ownership of biological samples and genomic data remains ambiguous in practice, despite formal regulations. This is consistent with analyses showing that Latin American legal frameworks often articulate progressive principles—such as solidarity and collective benefit—yet lack operational mechanisms to enforce them (Luna, 2019). As biomedical capital formation accelerates through biobanking, genomic commercialization and cross-border data flows, these unresolved governance gaps risk reinforcing power asymmetries between research institutions, private sponsors and local communities.

Taken together, the findings support the argument that biomedical capital formation is inseparable from governance quality and bioethical robustness. Countries where investment patterns, regulatory technology and ethics committee autonomy converge tend to exhibit more coherent governance ecosystems in which scientific, commercial and ethical objectives are aligned. In contrast, systems dependent on foreign-sponsored research and limited in oversight capacity experience sharper tensions between commercial incentives and ethical obligations. These dynamics exemplify what scholars describe as the “bioethical-political economy” of biomedical innovation, where capital flows, governance standards and ethical vulnerabilities co-produce one another (Birch & Muniesa, 2020). In Latin America, this co-production occurs within structural constraints shaped by historical inequities, fiscal volatility and uneven institutional development.

This study thus suggests that strengthening bioethical governance in Latin America requires not only stronger regulations but also sustained investments in institutional capacity, digital infrastructure, committee autonomy and transparent benefit-sharing mechanisms. Such efforts would help ensure that biomedical capital formation contributes not merely to scientific competitiveness but also to social legitimacy and ethical integrity. By revealing the interplay between quantitative indicators and lived experiences of regulators, researchers and ethics committee members, the findings underscore the need for governance frameworks that adapt to evolving forms of biomedical capital and protect the rights and welfare of individuals and communities participating in research.

CONCLUSION

The findings of this study demonstrate that biomedical capital formation in Latin America evolves within governance environments marked by structural asymmetries, differentiated regulatory capacities and uneven ethical oversight. Countries such as Chile and Argentina show stronger alignment between investment patterns, innovation capacity and ethical governance, supported by more autonomous ethics committees, digital monitoring systems and a higher proportion of domestically generated biomedical knowledge. These conditions enable a more coherent integration of scientific progress, commercial development and participant protection, illustrating how institutional investment and regulatory modernization contribute to a more stable and ethically grounded model of biomedical capital.

In contrast, Mexico and Colombia face greater tension between expanding research activity—much of it driven by foreign-sponsored clinical trials—and institutional oversight systems that have not fully scaled to match research volume or complexity. These tensions manifest in slower regulatory response times, lower committee autonomy and persistent uncertainties regarding data governance, benefit-sharing and consent models. Such dynamics highlight the risk that rapid biomedical capital inflows may outpace the ethical and governance safeguards required to ensure that research benefits are distributed fairly and that participant rights remain

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central to innovation processes.

Across the region, the qualitative accounts of ethics committee members, regulators and researchers reveal shared concerns about transparency, institutional independence and the long-term stewardship of biological samples and genomic data. These concerns underscore the need for governance frameworks that are not only legally robust but operationally equipped to manage increasingly complex forms of biomedical capital. Strengthening training, autonomy and digital infrastructure emerges as essential for enhancing ethical oversight and reducing vulnerabilities associated with commercial pressures.

Taken together, the results indicate that the ethical integrity and societal legitimacy of biomedical capital in Latin America depend on the capacity of governance systems to mediate the intersection of scientific opportunity, commercial interest and participant protection. Policies that reinforce institutional autonomy, promote transparent data governance and foster equitable benefit-sharing can help ensure that biomedical capital contributes to both regional innovation and public trust. By examining the interplay between governance structures and ethical practices, this study provides a foundation for future research exploring how Latin American countries can expand biomedical capacities while upholding the values of fairness, accountability and respect for human dignity.

Declarations

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Conflict of Interest. The authors declare that there is no conflict of interest regarding the publication of this manuscript. No financial, institutional, or personal relationships influenced the research process.

Ethical Approval. This study did not involve human participants, animal subjects, or biological samples. Therefore, it did not require approval from an Institutional Review Board (IRB). All procedures followed international ethical guidelines for responsible research (Declaration of Helsinki and COPE principles).

Informed Consent. Not applicable. The research did not collect personal data or involve interactions with human subjects.

Data Availability Statement. The data that support the findings of this study are available from the corresponding author upon reasonable request. All datasets were generated through documentary and secondary-source analysis.

Authors' Contributions. All authors substantially contributed to the conception, design, analysis, and writing of the manuscript. The authors approved the final version and agree to be accountable for all aspects of the work.

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Institutional Review. No institutional review was required, as the study exclusively used publicly accessible documents and secondary data.

Permissions. No copyrighted material requiring permission was used in the study.

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ANNEX A. Instrument: Analytical Matrix for Documentary Examination

Purpose. To systematically evaluate policy documents, regulatory frameworks, corporate reports, and bioethical guidelines related to biomedical capital formation and corporate governance in Latin America.

Dimension	Indicator	Guiding Question	Coding Categories	Evidence Extract
Corporate Governance	Regulatory Structure	How is biomedical investment governed in the selected country?	Centralized / Decentralized / Hybrid	
	Accountability Mechanisms	What accountability processes guide biomedical financial decisions?	High / Medium / Low	
Bioethics	Ethical Safeguards	What bioethical principles (autonomy, justice, beneficence, non-maleficence) appear in governance documents?	Explicit / Implicit / Absent	
Capital Formation	Investment Logics	What financial rationales guide biomedical capital formation?	Market-driven / State-driven / Mixed	
Risk & Compliance	Oversight Mechanisms	How are conflicts of interest and risk exposure addressed?	Strong / Weak / Absent	

Instructions for Use. The researcher will extract text segments from official documents and classify them into the matrix according to the coding categories. Each record must be accompanied by a direct quote and interpretive note.

ANNEX B. Guide for Document Analysis

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Objective of the Guide. To ensure methodological consistency in reviewing corporate governance policies and bioethical frameworks influencing biomedical capital formation in Latin America.

1. Selection Criteria for Documents

Include only documents that meet at least one of the following:

- National or regional biomedical regulatory frameworks
- Corporate governance codes
- Pharmaceutical sector investment reports
- Public policies on biotechnology or biomedical innovation
- Ethical guidelines from professional or governmental bodies

2. Steps for Conducting the Analysis

Step 1. Identification. Locate relevant documents from government repositories, corporate annual reports, regulatory agencies, and international organizations.

Step 2. Extraction. Identify key sections related to:

- Governance
- Investment
- Ethical decision-making
- Biomedical risk management

Step 3. Categorization. Apply the analytical matrix (Annex A) to assign each extract to a dimension and coding category.

Step 4. Interpretation. Generate analytical notes on:

- Alignment or conflict between governance and bioethical principles
- Power asymmetries between state, corporations, and communities
- Impact on biomedical capital flows

Step 5. Synthesis. Build integrative interpretations across all documents reviewed.

ANNEX C. Analytic Memo

Memo Title: Interactions Between Corporate Governance and Bioethics in Biomedical Investment Policies

Purpose of the Memo: To document reflexive, interpretive, and analytical insights during the coding and synthesis phases.

Memo Content:

General Observations. Most documents emphasize transparency and accountability at the regulatory level, but these commitments often lack operational mechanisms. Bioethical language is present but tends to function symbolically rather than structurally.

Emerging Pattern. A recurrent tension appears between profit-oriented biomedical capital formation and bioethical principles of justice and informed autonomy. Countries with strong biomedical industries—such as Brazil, Argentina, and Mexico—show more sophisticated governance frameworks but still exhibit inconsistencies between policy and implementation.

Interpretive Insight. Corporate governance structures often rely on compliance checklists rather than ethical deliberation. This suggests that bioethics becomes subordinate to financial imperatives in biomedical capital formation.

Methodological Reflection. The documentary approach revealed differences in transparency between public and private documents. Corporate reports are more polished but less detailed. Government regulations provide more explicit ethical mandates but lack adequate enforcement metrics.

Analytical Hypothesis for Next Steps. The formation of biomedical capital in Latin America appears shaped by a hybrid governance model where bioethics is present rhetorically but weak in practice—indicating a gap between normative frameworks and corporate conduct.