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ESPECIAL

Public policy for integrating molecular tumor biology in oncology practice: lessons from international frameworks and a roadmap for Latin America

Políticas públicas para la integración de la biología molecular tumoral en la práctica oncológica: lecciones de los marcos internacionales y una hoja de ruta para América Latina

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Abstract

Background: advances in molecular tumor biology have transformed oncology by enabling biomarker-driven approaches to diagnosis, prognosis, and therapy. However, integrating these innovations into routine practice depends heavily on public policy frameworks that govern test validation, reimbursement, and equitable access.

Objective: this review examines international experiences with biomarker policy in oncology, evaluates the current landscape in Latin America, and proposes a roadmap for equitable adoption of molecular tumor biology in the region.

Approach: a narrative review of peer-reviewed literature and authoritative policy documents was conducted. Frameworks from the United States, Canada, and the European Union were analyzed for regulatory, reimbursement, and health technology assessment (HTA) strategies. Latin American evidence was synthesized through published studies and regional reports on coverage, judicialization, and infrastructure.

Results: in high-income countries, biomarker integration is supported by strong regulatory over-

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sight, structured HTA, and reimbursement mechanisms, though access remains uneven. In Latin America, access is fragmented, with significant disparities between public and private sectors. Barriers include limited reimbursement, scarce laboratory infrastructure, workforce shortages, and the absence of standardized regulatory frameworks. Judicialization has become a common but inequitable pathway to access. Opportunities exist in leveraging regional collaborations, biobank development, and harmonized data governance.

Conclusions: policy innovation is essential to ensure equitable precision oncology in Latin America. A staged roadmap is proposed that spans regulatory clarity, pilot reimbursement, workforce training, and long-term regional harmonization. Preparing for emerging technologies such as liquid biopsy and tumor-agnostic therapies will be critical to avoid widening disparities and to realize the full potential of molecular tumor biology in the region.

Keywords: public policy; molecular biology; biomarkers; Latin America; disparities.

Resumen

Antecedentes: los avances en biología molecular tumoral han transformado la oncología al permitir enfoques de intervención basados en biomarcadores para el diagnóstico, el pronóstico y el tratamiento. Sin embargo, la integración de estas innovaciones en la práctica clínica habitual depende en gran medida de los marcos de políticas públicas que regulan la validación de pruebas, el reembolso y el acceso equitativo.

Objetivo: esta revisión examina las experiencias internacionales sobre políticas relativas al uso de biomarcadores en oncología, evalúa el panorama actual en América Latina y propone una hoja de ruta para la adopción equitativa de la biología molecular tumoral en la región.

Enfoque: se realizó una revisión narrativa de la literatura revisada por pares y de documentos de políticas de referencia. Se analizaron los marcos regulatorios de Estados Unidos, Canadá y la Unión Europea para estrategias de reembolso y evaluación de tecnologías sanitarias (ETS). La evidencia latinoamericana se sintetizó a partir de estudios publicados e informes regionales sobre cobertura, judicialización e infraestructura.

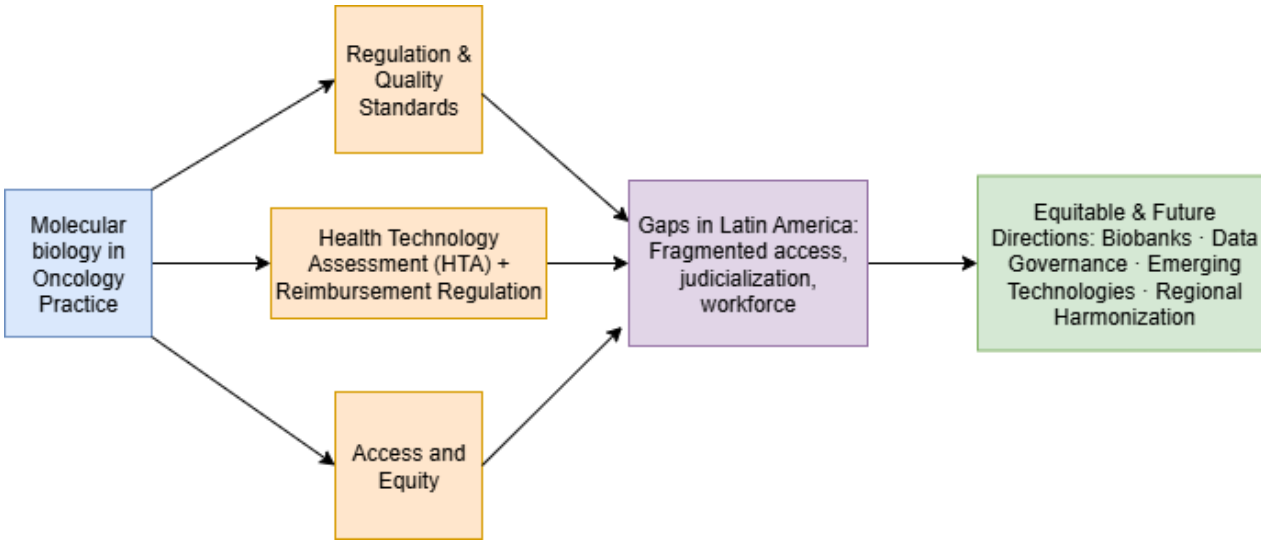
Resultados: en los países de altos ingresos, la integración de biomarcadores se apoya en una sólida supervisión regulatoria, una ETS estructurada y mecanismos de reembolso, aunque el acceso sigue siendo desigual. En América Latina, el acceso está fragmentado, con importantes disparidades entre los sectores público y privado. Las barreras incluyen reembolsos limitados, infraestructura de laboratorios deficiente, escasez de personal y la ausencia de marcos regulatorios estandarizados. La judicialización se ha convertido en una vía de acceso común, pero inequitativa. Existen oportunidades para aprovechar las colaboraciones regionales, el desarrollo de biobancos y la gobernanza armonizada de datos.

Conclusiones: la innovación en políticas es esencial para garantizar una oncología de precisión equi-

tativa en América Latina. Se propone una hoja de ruta en etapas que abarca la claridad regulatoria, el reembolso piloto, la capacitación del personal y la armonización regional a largo plazo. La preparación para tecnologías emergentes, como la biopsia líquida y las terapias agnósticas para tumores, será fundamental para evitar el aumento de las disparidades y aprovechar al máximo el potencial de la biología molecular tumoral en la región.

Palabras clave: políticas públicas; biología molecular; biomarcadores, América Latina, disparidades.

Graphical abstract



Key points

- Molecular tumor biology is reshaping oncology, but its integration into practice depends on clear policy frameworks for regulation, reimbursement, and equitable access.
- High-income countries have developed structured models and essential policy strategies such as strong regulatory oversight of diagnostics, structured health technology assessment (HTA), and reimbursement mechanisms that link testing to therapeutic value.
- Latin America faces fragmented and inequitable adoption, with limited reimbursement, concentration of testing capacity in urban centers, and reliance on judicialization to secure access.
- Complementary enablers such as biobanks and data governance remain underdeveloped in the Latin American region, limiting both research capacity and clinical implementation.
- A staged policy roadmap is proposed for Latin America, including regulatory clarity, pilot reimbursement, equity safeguards, workforce training, regional HTA harmonization, and preparation for emerging technologies such as liquid biopsy and tumor-agnostic therapies.

Introduction

Molecular tumor biology has fundamentally transformed the practice of oncology[1]. By identifying the genomic alterations that drive tumor initiation and progression, clinicians can use biomarkers to predict prognosis, refine risk stratification, and guide targeted therapy selection[2]. Technologies such as next-generation sequencing (NGS), polymerase chain reaction (PCR), and fluorescence in situ hybridization (FISH) now enable the simultaneous detection of multiple clinically relevant biomarkers across solid tumors and hematologic malignancies[3,4]. These innovations have underpinned the emergence of precision oncology, with demonstrated improvements in patient outcomes and cost efficiency through tailored therapy allocation[5].

However, the full realization of molecular tumor biology depends on policy frameworks that regulate test development, establish reimbursement pathways, and ensure equitable access. In high-income countries, these frameworks have been shaped by regulatory agencies, health technology assessment (HTA) bodies, and professional societies. In the United States, the Food and Drug Administration (FDA) evaluates companion diagnostics. At the same time, the Centers for Medicare & Medicaid Services (CMS) has issued a national coverage determination (NCD) for NGS testing in advanced cancer[6]. In Europe, the European Society for Medical Oncology (ESMO) has issued recommendations on genomic testing and molecular tumor boards, and the European Union recently adopted Regulation 2021/2282 on joint clinical assessments of health technologies, with oncology prioritized for implementation[7–9]. Canada, through the Canadian Agency for Drugs and Technologies in Health (CADTH), has drafted an assessment framework to evaluate biomarkers used in cancer care, integrating considerations of clinical validity, clinical utility, cost-effectiveness, and system readiness[10].

Despite these advances, several systemic challenges persist. Even in countries with established policies, evidence gaps around clinical utility, heterogeneity in laboratory accreditation, and payer variability hinder uniform adoption of biomarker testing[7,11,12]. Moreover, the costs of testing and targeted therapies raise sustainability concerns for health systems, making HTA and value-assessment frameworks essential[13]. These challenges highlight the interdependence of science, policy, and economics in translating molecular biology into practice.

Across Latin America, access to biomarker testing is fragmented and shaped by disparities in healthcare financing, infrastructure, and workforce capacity[14]. Studies show that in Brazil's public system (Sistema Único de Saúde), fewer than half of patients with non-small cell lung cancer (NSCLC) receive biomarker testing despite actionable mutations being prevalent[15]. In Colombia, comprehensive genomic profiling has recently been piloted, but coverage remains partial, and patients often resort to judicial action (*tutelas*) to secure access[16,17]. Regional analyses confirm that inequities exist not only between public and private sectors but also across urban and rural populations, compounding delays in diagnosis and limiting access to novel targeted therapies[18–21].

Beyond access, structural barriers include the absence of standardized regulatory frameworks for biomarker validation, limited investment in laboratory capacity, and shortages of trained professionals in molecular pathology and clinical genetics[19]. Addressing these barriers requires policy interventions tailored to the socioeconomic context of Latin American health systems. Lessons from high-income settings provide useful benchmarks but must be adapted to local realities of resource constraints and fragmented governance. The integration of molecular tumor biology into oncology prac-

tice will depend on aligning regulatory clarity, economic evaluation, equitable access strategies, and regional capacity-building.

This review therefore aims to: (i) synthesize international experiences in biomarker policy and reimbursement, (ii) describe the current landscape and challenges in Latin America, (iii) highlight complementary areas such as biobanking and data governance, and (iv) propose a roadmap for policy development that supports equitable precision oncology in the region.

International policy frameworks on cancer biomarkers

The successful integration of molecular tumor biology into oncology practice has required clear policy frameworks to guide regulatory approval, reimbursement, and clinical implementation of biomarker testing. High-income countries have taken varying approaches to establishing these frameworks. Still, certain common elements stand out: (i) regulatory oversight of test validity and companion diagnostics, (ii) mechanisms to determine clinical utility and cost-effectiveness, (iii) laboratory quality standards, and (iv) reimbursement pathways aligned with payer systems.

United States

In the United States, policy for biomarker integration has been strongly influenced by the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA). The FDA regulates the approval of companion diagnostics, ensuring that molecular tests are analytically valid and linked to specific therapeutic indications[4]. A landmark moment came in 2018 when CMS issued a National Coverage Determination (NCD) for NGS in advanced cancer. This policy granted national coverage for FDA-approved or -cleared NGS tests performed in Clinical Laboratory Improvement Amendments-certified laboratories, ordered by treating physicians, and used to guide treatment for recurrent, relapsed, refractory, metastatic, or advanced solid tumors[22].

The NCD was notable for embedding strict conditions: coverage was restricted to patients with advanced disease and required the test to be approved as a companion diagnostic. Non-FDA-approved tests or laboratory-developed tests (LDTs) remained subject to local coverage decisions by Medicare Administrative Contractors (MACs), generating regional variability[22,23]. This dual structure illustrates how, even under a federal policy, access may and most likely will depend on local payer interpretation. Private payers have adopted heterogeneous coverage frameworks. Analyses of insurer behavior reveal that decisions often rely on three pillars: analytic validity (is the test accurate and reproducible?), clinical validity (is the biomarker reliably associated with a clinical outcome?), and clinical utility (does using the test improve patient outcomes?)[24]. For multigene panels, payers frequently require evidence that at least a subset of genes has proven clinical utility, leaving many panels only partially covered[25].

CMS has also established granular coverage policies through its Molecular Diagnostics (MolDX) program, which includes local coverage determinations (LCDs) for specific assays. For example, a 2025 LCD restricted coverage for biomarker detection in circulating tumor cells to tests that meet rigorous clinical utility and analytic criteria[26]. These policies underscore the importance of evidence thresholds in reimbursement and the tension between rapidly evolving science and payer requirements. In parallel, the United States has invested in national precision oncology programs such as the NCI-MATCH trial[27], which generates real-world evidence for biomarker-guided therapies, highlighting the advantages of targeted therapies in optimizing

patient outcomes. These initiatives inform policy by providing data on clinical utility and cost-effectiveness, thereby shaping payer decisions.

Canada

Canada has taken a structured HTA-driven approach. The Canadian Agency for Drugs and Technologies in Health (CADTH) plays a central role in informing provincial-level decisions, as healthcare delivery and reimbursement are organized provincially. In 2025, CADTH released a draft Assessment Framework for Biomarkers in Cancer Care, which formalized a set of domains to guide policy: (i) analytic validity, (ii) clinical validity, (iii) clinical utility, (iv) cost and budget impact, (v) ethical, legal, and social implications, (vi) system readiness, and (vii) equity[10].

This framework acknowledges that, beyond scientific validity, the successful adoption of biomarkers requires infrastructure (laboratory capacity and trained personnel) and system alignment (clinical guidelines and reimbursement models). Notably, CADTH included "equity" as a domain, recognizing disparities in access across Canada's provinces and Indigenous populations[10]. Despite this progress, variability remains in biomarker adoption across provinces. While some jurisdictions fund broad NGS panels, others limit coverage to selected single-gene tests. This reflects differing provincial HTA assessments and budgetary constraints, highlighting the challenges of decentralized healthcare systems. Canadian oncologists have expressed concern about these inequities, which create regional differences in patient access to precision oncology[18].

European Union

The European Union (EU) has developed multiple, overlapping policy frameworks to support the adoption of biomarkers. A significant milestone was the Health Technology Assessment (HTA) Regulation 2021/2282, which introduced mandatory Joint Clinical Assessments (JCAs) for selected health technologies, including oncology diagnostics[9]. The regulation, fully effective from 2025, requires EU member states to collaborate on evaluating clinical evidence for biomarkers and therapies, aiming to reduce duplication and accelerate patient access.

Complementing regulatory initiatives, professional societies such as the European Society for Medical Oncology (ESMO) have issued detailed recommendations. In 2022, ESMO published a position paper on genomic testing, emphasizing the importance of multigene NGS in advanced cancers with multiple actionable biomarkers[11]. In 2024, updated guidelines recommended standardized reporting of genomic results, specifying which findings should be considered "essential" versus "optional" in clinical practice[4]. In 2025, ESMO's Precision Oncology Working Group proposed quality indicators for molecular tumor boards (MTBs), recognizing them as critical infrastructures for translating biomarker results into therapeutic decisions[8].

Real-world data confirm that there is significant variation in biomarker access across Europe. A 2022 survey across 10 countries found substantial gaps in testing rates for EGFR, ALK, and PD-L1 in NSCLC, with delays and inequities between academic and community centers[11]. Country-level examples illustrate diverse strategies:

- **France's Institut National du Cancer (INCa)** has established national funding for molecular testing, ensuring universal access to specific biomarkers.

- **Germany** reimburses biomarker testing through diagnosis-related group (DRG)

payments, but access may vary across federal states.

- **United Kingdom (NICE)** assesses companion diagnostics within its Diagnostics Assessment Programme, explicitly linking reimbursement to clinical and cost-effectiveness evidence[28–30].

Taken together, the experiences of the United States, Canada, and the European Union illustrate both convergence and divergence in how high-income health systems have approached biomarker integration. All three have established strong regulatory oversight and some form of evidence evaluation. Yet, differences remain in reimbursement mechanisms, the role of centralized HTA, and the extent to which equity is addressed explicitly. These contrasts are summarized in Table 1, which provides a comparative snapshot of policy maturity across key domains. Abbreviations are expanded in the table footnote. This synthesis highlights the multidimensional nature of biomarker policy and underscores the importance of adapting international lessons to regional contexts such as Latin America.

Table 1.

Comparative strength of biomarker policy frameworks in oncology

Policy domain	United States	Canada	European Union
Regulatory authority	FDA approvals; CLIA lab standards (robust)	Health Canada; provincial oversight (moderate)	EMA approvals; ISO lab standards (robust)
Reimbursement mechanism	CMS NCD for NGS; LCDs; fragmented private payer coverage (variable/fragmented)	Provincial funding; significant variability (fragmented)	Country-specific (France centralized, Germany DRG-based, UK NICE) (heterogeneous)
HTA / evaluation role	No centralized HTA; payer-driven evidence appraisal (weakly structured)	CADTH biomarker framework (draft, 2025) (emerging/structured)	EU HTA Regulation mandates Joint Clinical Assessments from 2025 (emerging/harmonizing)
Equity considerations	Coverage limited to advanced disease; payer disparities (limited equity)	Equity is explicit in the CADTH framework, but uneven implementation (explicit but weakly applied)	Marked cross-country gaps; east–west disparities (variable)
Clinical integration	National trials (NCI-MATCH); MTBs mainly in academic centers (selective)	pCODR links therapy/biomarker decisions; pilots of NGS in some provinces (patchy integration)	ESMO guidelines; France INCa national testing; NICE Diagnostics (well-integrated in selected countries)

Note: Evaluative descriptors: robust, fragmented, emerging reflect relative policy maturity and integration strength across regulatory, reimbursement, HTA, equity, and clinical practice domains. FDA= Food and Drug Administration, CLIA= Clinical Laboratory Improvement Amendments, CMS= Centers for Medicare & Medicaid Services, NCD= National Coverage Determination LCD, Local Coverage Determination; EMA, European Medicines Agency; ISO= International Organization for Standardization; CADTH= Canadian Agency for Drugs and Technologies in Health, HTA= Health Technology Assessment; JCA= Joint Clinical Assessment, Pcodr= pan-Canadian Oncology Drug Review, NGS= Next-Generation Sequencing, MTBs= Molecular Tumor Boards.

Current landscape in Latin America

Latin America faces a dual challenge in precision oncology: rapidly rising cancer incidence and mortality, coupled with limited health system capacity to incorporate advanced molecular technologies. The region accounts for approximately 7% of the global cancer burden, but inequities in prevention, diagnosis, and treatment contribute to worse outcomes compared with high-income countries[18,20]. Precision oncology has the potential to narrow these gaps by tailoring therapies to tumor biology; however, the adoption of molecular biomarkers has been slow, fragmented, and often limited to the private sector[18,19,31]. Regional analyses highlight systemic barriers. Laboratories capable of performing next-generation sequencing (NGS) or broad molecular profiling are concentrated in a few urban centers, creating geographic inequalities[32]. Public reimbursement for biomarker testing is rare, leaving patients in many countries to pay out of pocket or rely on judicial recourse to obtain coverage[17,33]. The lack of standardized regulatory frameworks for biomarker validation and incorporation into clinical guidelines further constrains uptake[18,34].

Brazil

Brazil has one of the most developed oncology infrastructures in Latin America, yet integration of biomarker testing into the Unified Health System remains limited[35]. A 2025 study of patients with non-small cell lung cancer (NSCLC) treated in SUS found that fewer than half received testing for actionable biomarkers such as EGFR, ALK, or PD-L1, despite the high prevalence of targetable mutations[15]. Barriers include inadequate reimbursement, limited laboratory capacity outside major cities, and long turnaround times[36]. Policy debates in Brazil have also highlighted the "judicialization" phenomenon, in which patients gain access to molecular tests or targeted therapies through lawsuits against the public health system[17,37]. While this mechanism secures access for some, it exacerbates inequities by favoring those with legal resources. At the same time, the private sector offers more comprehensive genomic profiling, widening the public–private gap[38]. Recent policy discussions call for expanding coverage within SUS and incorporating precision oncology into national cancer plans, but implementation has been slow[19].

Mexico

In Mexico, molecular testing is available in tertiary hospitals and private laboratories, but access in the public sector is restricted[18]. Comprehensive NGS panels are not routinely reimbursed, and only selected biomarkers (e.g., HER2, EGFR) are covered in specific contexts. Patients often face high out-of-pocket costs or delays in obtaining results[19]. The fragmentation of the Mexican health system complicates the development of national policy. Although the Ministry of Health has recognized precision oncology as a strategic priority, implementation remains pilot-based rather than systemwide[39]. Academic centers in Mexico City and Monterrey have pioneered local molecular tumor boards, but their impact is limited geographically[19].

Colombia

Colombia illustrates both opportunities and barriers. In 2024, researchers reported the country's first experience with comprehensive genomic profiling (CGP) in oncology, showing that results influenced therapeutic decision-making in a significant proportion of patients[16]. Yet coverage for such testing under the Plan de Beneficios en Salud (PBS) remains partial, and patients frequently resort to tutela actions, which are constitutional lawsuits, to secure access to biomarker testing or targeted therapies[17]. This reliance on judicialization reflects broader structural issues in Colombia's health system, including gaps in technology assessment and insufficient inclu-

sion of biomarkers in national guidelines. While oncology centers in Bogotá and Medellín have begun offering molecular profiling, access is far more limited in rural regions[17,18].

Argentina, Chile, and Peru

Argentina has seen growing adoption of molecular testing in private hospitals, but integration into the public system remains inconsistent[40]. Judicialization of access to targeted therapies and diagnostics has also been documented, mirroring patterns in Brazil and Colombia[18]. Chile has piloted NGS testing in selected centers, but coverage under public insurance (FONASA) is limited. National cancer plans have mentioned precision oncology as a future priority, but resource constraints hinder widespread implementation[41]. Peru's health system, characterized by fragmentation across public and private insurers, faces significant challenges in incorporating biomarkers. Access is primarily restricted to private laboratories, and delays in pathology services remain significant[20].

Cross-cutting themes

Across Latin America, several recurring challenges emerge:

- **Financing and reimbursement:** Few countries include biomarker testing in their essential benefits packages; most require out-of-pocket payment or litigation.
- **Infrastructure:** Limited NGS capacity and uneven distribution of laboratories across urban vs. rural areas.
- **Workforce:** Shortages of molecular pathologists, genetic counselors, and bioinformaticians.
- **Regulation:** Absence of standardized frameworks for test validation, HTA, and integration into guidelines.
- **Equity:** Public–private gaps, judicialization, and geographic disparities exacerbate inequities.
- **Data governance and biobanks:** Minimal infrastructure for storing and sharing genomic data.

Despite these barriers, there are emerging opportunities. Regional collaborations, such as networks of cancer registries and PAHO's Code Against Cancer in Latin America and the Caribbean, provide platforms for integrating molecular diagnostics into broader cancer control policies[42]. Pilot projects in Brazil, Mexico, and Colombia demonstrate feasibility, even if scaling remains challenging[15,16]. Latin America demonstrates significant heterogeneity in the adoption of molecular tumor biology. Brazil and Colombia have piloted biomarker programs, but access is inconsistent and often dependent on litigation. Mexico and Argentina face fragmentation across public and private sectors, while Chile and Peru remain at the pilot stage. Across all countries, common barriers include limited reimbursement, infrastructure concentration in urban centers, shortages of trained personnel, and the absence of clear regulatory frameworks.

Complementary policy areas

The effective integration of molecular tumor biology into oncology does not depend solely on reimbursement and regulatory frameworks. Equally important are the enabling infrastructures that ensure high-quality samples, standardized testing, and secure use of genomic data. Biobanks and data governance frameworks serve as the backbone for both research and clinical translation, yet they remain underdeveloped in Latin America.

Biobanking as an enabler of precision oncology

Biobanks provide systematic collection, processing, storage, and distribution of biological specimens for clinical and research use. In high-income countries, large-scale initiatives such as BBMRI-ERIC (Biobanking and BioMolecular Resources Research Infrastructure – European Research Infrastructure Consortium) have established governance models for standardized sample access and sharing across multiple countries[29]. The BBMRI-ERIC policy framework emphasizes transparency, ethical oversight, and harmonized quality standards to ensure that biospecimens are suitable for downstream molecular analysis[43]. Similarly, the International Society for Biological and Environmental Repositories (ISBER) has developed best practice guidelines for biobank operations, now in their fifth edition, covering all aspects from sample collection to long-term preservation and quality control[44]. These global guidelines provide a benchmark for laboratories seeking accreditation and for policymakers integrating biobanks into national cancer strategies.

Latin America lacks large-scale regional biobank networks comparable to BBMRI-ERIC. While some national cancer institutes and academic centers in Brazil, Argentina, and Colombia maintain biorepositories, these initiatives are fragmented and often lack sustainable funding[16,18]. Limited adherence to international quality standards reduces the potential of these collections to support precision oncology or collaborative research. Strengthening biobanking capacity represents a critical step toward both clinical implementation of molecular testing and participation in international research consortia.

Data governance and ethical frameworks

Molecular testing generates sensitive genomic data that must be managed responsibly to protect patient privacy while enabling research and clinical use. The Global Alliance for Genomics and Health (GA4GH) developed a framework for the responsible sharing of genomic and health-related data, setting out principles of transparency, accountability, and respect for persons[30]. In Europe, data sharing is also shaped by the General Data Protection Regulation (GDPR), which has influenced global norms on privacy and secondary use of health data[28].

Latin American countries vary widely in how they govern genomic data. Brazil's General Data Protection Law (Lei Geral de Proteção de Dados, LGPD) provides some safeguards but does not explicitly address genomic data. Colombia and Mexico lack comprehensive regulations for genetic information, leaving governance to institutional review boards or ethics committees[17,21]. This regulatory vacuum hinders regional data integration and limits opportunities to participate in multicountry trials or international knowledge-sharing initiatives.

The absence of clear frameworks also raises equity concerns. Without robust protections, vulnerable populations may be reluctant to contribute biospecimens or genomic data, exacerbating underrepresentation in research. Conversely, overly restrictive rules could prevent cross-border data sharing and slow the development of regionally relevant precision oncology evidence. Balancing protection with access is therefore critical.

Opportunities for Latin America

Despite these challenges, there are promising opportunities for Latin America to strengthen biobanking and data governance. Several countries are beginning to adopt international standards, and regional collaborations—such as networks supported by the Pan American Health Organization—could provide platforms for harmonization [42]. Leveraging existing cancer registries as entry points for genomic data collection may also be feasible, particularly in

countries like Brazil and Colombia, where population-based registries already exist[15,16].

Integrating biobanks and data governance into national cancer control plans can yield multiple benefits: ensuring quality assurance for molecular testing, building trust among patients and providers, and enabling participation in international consortia. In turn, these steps would support the policy goal of equitable precision oncology by reducing reliance on external laboratories and improving regional capacity for evidence generation.

Policy proposals for Latin America

Rationale for a regional roadmap

Latin America stands at a crossroads in integrating molecular tumor biology into oncology practice. While the science of biomarker-driven therapies is rapidly advancing, the policy environment remains fragmented and underdeveloped. To avoid widening disparities in cancer outcomes, governments, professional societies, and regional organizations must implement coordinated strategies that address regulatory clarity, sustainable financing, and equitable access. Drawing from international frameworks and regional realities, we propose a roadmap for biomarker policy tailored to Latin America.

A foundational step is the creation of clear regulatory frameworks for biomarker validation and use. National regulatory agencies should establish processes for approving laboratory-developed tests and companion diagnostics that align with international standards (e.g., FDA, EMA, ISO). Accreditation of laboratories performing NGS must be enforced, ideally through regional collaboration to share resources for proficiency testing and quality audits[29,43]. Establishing national reference laboratories in strategic hubs could reduce redundancy, ensure quality, and expand access beyond major cities. To ensure sustainability, biomarkers should be evaluated using HTA frameworks that incorporate not only clinical validity and utility but also cost-effectiveness, budget impact, and equity considerations[45,46]. Latin American countries could adapt elements of the CADTH biomarker framework or EU Joint Clinical Assessments, while tailoring thresholds to local resource constraints [9,10]. Financing strategies may include:

- **Bundled reimbursement** models, where testing and therapy are jointly evaluated.
- **Risk-sharing agreements** with pharmaceutical companies to offset costs of testing.
- **Regional procurement mechanisms** to reduce test costs through pooled purchasing.

Equity must be a guiding principle in the integration of biomarkers. Policies should mandate coverage for essential biomarkers in national benefits packages, prioritizing high-prevalence cancers, such as breast, lung, and colorectal cancers. Governments should invest in expanding laboratory infrastructure outside urban centers and subsidize patient access in public systems[19,20,22]. Addressing judicialization requires proactive inclusion of biomarkers in benefit plans, reducing reliance on litigation as a pathway to access[25,37]. Policies should link biomarker testing directly to clinical decision-making. This includes updating national oncology guidelines to reflect evidence-based biomarker recommendations and institutionalizing molecular tumor boards (MTBs) to interpret complex genomic results[47]. Training programs for molecular pathologists, genetic counselors, and bioinformaticians must be scaled up, with academic–policy partnerships providing incentives for retention. Regional training networks, supported by PAHO, could pool expertise across countries.

As described in Section 4, strengthening biobanking and data governance is critical for building regional evidence. Policies should mandate quality standards for biospecimen handling and adopt frameworks such as GA4GH for responsible genomic data sharing[30]. Regional harmonization of data protection rules could facilitate participation in multicountry trials and generate real-world evidence to support HTA.

Conclusions

Molecular tumor biology has transformed oncology worldwide, but its equitable adoption in Latin America remains uneven. While international frameworks from the United States, Canada, and Europe demonstrate that regulatory clarity, structured HTA, and sustainable financing are feasible, adaptation to Latin American realities has lagged. As a result, access to biomarker testing is often dependent on private insurance or judicial action, leaving large segments of the population excluded.

To close this gap, governments and regional organizations must act decisively. In the short term, this means incorporating essential biomarkers into national benefit packages, enforcing laboratory quality standards, and piloting reimbursement models that link testing with therapy. Medium-term actions should expand molecular tumor boards, scale up workforce training, and harmonize data governance. Long-term goals include regional procurement mechanisms, interoperable biobanks, and joint HTA processes that align with international standards[48,49]. Looking ahead, Latin America must also prepare for the next generation of innovations, including liquid biopsy, tumor-agnostic therapies, and artificial intelligence–enabled diagnostics. These technologies will further expand the role of biomarkers in guiding treatment, but without forward-looking policies, they risk exacerbating current inequities. Ensuring equitable adoption will require political commitment, innovative financing, and sustained regional collaboration. By aligning scientific advances with policy innovation, Latin America has the opportunity not only to catch up but also to lead in developing models of equitable precision oncology tailored to middle-income health systems. The time to act is now, before disparities in cancer outcomes widen further.

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References

1. Mathur S, Sutton J. Personalized medicine could transform healthcare. Biomed Rep [Internet]. 2017;7(1):3–5. Available from: https://doi.org/10.3892/br.2017.922

2. Zhou Y, Tao L, Qiu J, Xu J, Yang X, Zhang Y, et al. Tumor biomarkers for diagnosis, prognosis and targeted therapy. Signal Transduct Target Ther [Internet]. 2024;9(1):132. Available from: https://www.nature.com/articles/s41392-024-01823-2

3. Schilsky RL. Personalized medicine in oncology: the future is now. Nat Rev Drug

Discov [Internet]. 2010;9(5):363–6. Available from: https://www.nature.com/articles/nrd3181

4. Purkayastha K, Dhar R, Pethusamy K, Srivastava T, Shankar A, Rath GK, et al. The issues and challenges with cancer biomarkers. J Cancer Res Ther [Internet]. 2023;19(Supplement):S20–35. Available from: https://doi.org/10.4103/jcrt.jcrt_384_22

5. Zou J, Wang E. Cancer Biomarker Discovery for Precision Medicine: New Progress. Curr Med Chem [Internet]. 2019;26(42):7655–71. Available from: https://doi.org/10.2174/0929867325666180718164712

6. Centers for Medicare & Medicaid Services. Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer [Internet]. 2018. Report No.: CAG-00450N. Available from: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=296&ExpandComments=n&NCDId=342&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7CNCD%7CMCD&KeyWord=uspstf&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAADgAAAAA

7. Normanno N, Apostolidis K, Wolf A, Al Dieri R, Deans Z, Fairley J, et al. Access and quality of biomarker testing for precision oncology in Europe. Eur J Cancer Oxf Engl [Internet]. 2022;176:70–7. Available from: https://doi.org/10.1016/j.ejca.2022.09.005

8. Westphalen CB, Boscolo Bielo L, Aftimos P, Beltran H, Benary M, Chakravarty D, et al. ESMO Precision Oncology Working Group recommendations on the structure and quality indicators for molecular tumour boards in clinical practice. Ann Oncol Off J Eur Soc Med Oncol [Internet]. 2025;36(6):614–25. Available from: https://doi.org/10.1016/j.annonc.2025.02.009

9. European Commission. Regulation on on health technology assessment [Internet]. 2021. Report No.: 2021/2282. Available from: https://eur-lex.europa.eu/eli/reg/2021/2282/oj/eng

10. CADTH Advisory Panel. Planning for a Coordinated Assessment Framework for Biomarkers Used in Cancer Care: A Report from the Biomarker Advisory Panel [Internet]. 2025. Report No.: CP0048-000. Available from: https://www.cda-amc.ca/sites/default/files/2025-08/CP0048-Biomarker-Assessment-Framework_DRAFT_V1.0_EN.pdf

11. Govaerts L, Simoens S, Van Dyck W, Huys I. Shedding Light on Reimbursement Policies of Companion Diagnostics in European Countries. Value Health J Int Soc Pharmacoeconomics Outcomes Res. 2020;23(5):606–15. Available from: https://doi.org/10.1016/j.jval.2020.01.013

12. DaCosta Byfield S, Bapat B, Becker L, Reyes C, Chatzitheofilou I, Schroeder BE, et al. Biomarker Testing Approaches, Treatment Selection, and Cost of Care Among Adults With Advanced Cancer. JAMA Netw Open [Internet]. 2025;8(7):e2519963. Available from: https://doi.org/10.1001/jamanetworkopen.2025.19963

13. Mirza M, Goerke L, Anderson A, Wilsdon T. Assessing the Cost-Effectiveness of Next-Generation Sequencing as a Biomarker Testing Approach in Oncology and Policy Implications: A Literature Review. Value Health [Internet]. 2024;27(9):1300–9. Available from: https://doi.org/10.1016/j.jval.2024.04.023

14. Piñeros M, Laversanne M, Barrios E, Cancela M de C, de Vries E, Pardo C, et al. An updated profile of the cancer burden, patterns and trends in Latin America and the Caribbean. Lancet Reg Health Am [Internet]. 2022;13. Available from: https://doi.org/10.1016/j.lana.2022.100294

15. Schneider LP, Maselli-Schoueri JH, Gutierres Aguiar B de S, Nazareth Aguiar P, Del Giglio A. Addressing challenges in the implementation of precision oncology: An in-depth examination of limitations and disparities in the treatment of non-small cell lung cancer in the Brazilian public healthcare system (SUS). Glob Public Health [Internet]. 2025;20(1):2450412. Available from: https://doi.org/10.1080/17441692.2025.2450412

16. López Rivera JJ, Rueda-Gaitán P, Rios Pinto LC, Rodríguez Gutiérrez DA, Gomez-Lopera N, Lamilla J, et al. Advancing Cancer Care in Colombia: Results of the First In Situ Implementation of Comprehensive Genomic Profiling. J Pers Med [Internet]. 2024;14(9):975. Available from: https://doi.org/10.3390/jpm14090975

17. Vargas-Pelaez CM, Rover MRM, Soares L, Blatt CR, Mantel-Teeuwisse AK, Rossi FA, et al. Judicialization of access to medicines in four Latin American countries: a comparative qualitative analysis. Int J Equity Health [Internet]. 2019;18(1):68. Available from: https://doi.org/10.1186/s12939-019-0960-z

18. González AR, Merchán LAA, Alexander JAA, Kaen D, Lopez-Correa C, Martin C, et al. Precision Medicine for Cancer and Health Equity in Latin America: Generating Understanding for Policy and Health System Shaping. Int J Environ Res Public Health [Internet]. 2025;22(8):1220. Available from: https://www.mdpi.com/1660-4601/22/8/1220

19. de Castilla EMR, Mayrides M, González H, Vidangossy F, Corbeaux T, Ortiz N, et al. Implementing precision oncology in Latin America to improve patient outcomes: the status quo and a call to action for key stakeholders and decision-makers. Ecancermedicalscience [Internet]. 2024;18:1653. Available from: https://doi.org/10.3332/ecancer.2024.1653

20. Llera AS. A fresh perspective on Latin America cancer care: uncovering hidden messages in unconventional data sources. Lancet Reg Health Am [Internet]. 2023;24:100559. Available from: https://doi.org/10.1016/j.lana.2023.100559

21. Torres-Narvaez ES, Mendivelso-González DF, Artunduaga-Alvarado JA, Ortega-Recalde O. Cancer genomics and bioinformatics in Latin American countries: applications, challenges, and perspectives. Front Oncol [Internet]. 2025;15:1584178. Available from: https://doi.org/10.3389/fonc.2025.1584178

22. CMS. Next Generation Sequencing (NGS): Testing in advanced cancers [Internet]. 2018. Report No.: 100–3. Available from: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R215NCD.pdf

23. Sheinson DM, Wong WB, Flores C, Ogale S, Gross CP. Association Between Medicare's National Coverage Determination and Utilization of Next-Generation Sequencing. JCO Oncol Pract [Internet]. 2021;17(11):e1774–84. Available from: https://ascopubs.org/doi/10.1200/OP.20.01023

24. Trosman JR, Weldon CB, Gradishar WJ, Benson AB, Cristofanilli M, Kurian AW, et al. From the Past to the Present: Insurer Coverage Frameworks for Next-Generation Tumor Sequencing. Value Health J

Int Soc Pharmacoeconomics Outcomes Res [Internet]. 2018;21(9):1062–8. Available from: https://doi.org/10.1016/j.jval.2018.06.011

25. Trosman JR, Weldon CB, Douglas MP, Kurian AW, Kelley RK, Deverka PA, et al. Payer Coverage for Hereditary Cancer Panels: Barriers, Opportunities, and Implications for the Precision Medicine Initiative. J Natl Compr Cancer Netw JNCCN [Internet]. 2017;15(2):219–28. Available from: https://doi.org/10.6004/jnccn.2017.0022

26. CMS. MolDX: Phenotypic Biomarker Detection in Circulating Tumor Cells. Report No.: LCD ID L38566. 2021. Available from: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38566

27. O'Dwyer PJ, Gray RJ, Flaherty KT, Chen AP, Li S, Wang V, et al. The NCI-MATCH trial: lessons for precision oncology. Nat Med [Internet]. 2023;29(6):1349–57. Available from: https://doi.org/10.1038/s41591-023-02379-4

28. Kaye J, Briceño Moraia L, Mitchell C, Bell J, Bovenberg JA, Tassé AM, et al. Access Governance for Biobanks: The Case of the BioSHaRE-EU Cohorts. Biopreservation Biobanking [Internet]. 2016 June;14(3):201–6. Available from: https://doi.org/10.1089/bio.2015.0124

29. Reihs R, Proynova R, Maqsood S, Ataian M, Lablans M, Quinlan PR, et al. BBMRI-ERIC Negotiator: Implementing Efficient Access to Biobanks. Biopreservation Biobanking [Internet]. 2021;19(5):414–21. Available from: https://doi.org/10.1089/bio.2020.0144

30. Knoppers BM. Framework for responsible sharing of genomic and health-related data. HUGO J [Internet]. 2014;8(1):3. Available from: https://doi.org/10.1186/s11568-014-0003-1

31. Dienstmann R. WS04.02 Access to Biomarker Testing in Latin America. J Thorac Oncol [Internet]. 2021;16(10):S842. Available from: https://doi.org/10.1016/j.jtho.2021.08.759

32. Arai RJ, Guindalini RSC, Llera AS, O'Connor JM, Muller B, Lema M, et al. Personalizing Precision Oncology Clinical Trials in Latin America: An Expert Panel on Challenges and Opportunities. The Oncologist [Internet]. 2019;24(8):e709–19. Available from: https://doi.org/ 10.1634/theoncologist.2018-0318

33. Ginsburg GS, Phillips KA. Precision Medicine: From Science To Value. Health Aff Proj Hope [Internet]. 2018;37(5):694–701. Available from: https://doi.org/10.1377/hlthaff.2017.1624

34. Alvarado-Cabrero I, Doimi F, Ortega V, de Oliveira Lima JT, Torres R, Torregrosa L. Recommendations for streamlining precision medicine in breast cancer care in Latin America. Cancer Rep Hoboken NJ [Internet]. 2021;4(6):e1400. Available from: https://doi.org/10.1002/cnr2.1400

35. International Agency for Research on Cancer Global Cancer Observatory in Brazil. 2024. Available from: https://gco.iarc.who.int/media/globocan/factsheets/populations/76-brazil-fact-sheet.pdf.

36. Duarte FA, Ferreira CG, Dienstmann R, Ferrari BL, Costa E Silva M, Nazareth A Junior P, et al. Barriers in precision medicine implementation among Advanced Nonsquamous Cell Lung Cancer-patients: A Real-World Evidence Scenario. J Mark Access Health Policy [Internet]. 2022;10(1):2077905. Available from: https://doi.org/10.1080/20016689.2022.2077905

37. World Health Organization. Health technology assessment of medical devices [Internet]. 2024. Report No.: 2. Available from: https://iris.who.int/server/api/core/bitstreams/68a45b5a-97a6-44e1-b3bf-8cb39cc460f3/content

38. Eichler HG, Trusheim M, Schwarzer-Daum B, Larholt K, Zeitlinger M, Brunninger M, et al. Precision Reimbursement for Precision Medicine: Using Real-World Evidence to Evolve From Trial-and-Project to Track-and-Pay to Learn-and-Predict. Clin Pharmacol Ther [Internet]. 2022;111(1):52–62. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/cpt.2471

39. Moye-Holz D, Soria Saucedo R, van Dijk JP, Reijneveld SA, Hogerzeil HV. Access to innovative cancer medicines in a middle-income country - the case of Mexico. J Pharm Policy Pract [Internet]. 2018;11:25. Available from: https://doi.org/10.1186/s40545-018-0153-y

40. Mapa de accionabilidad genómica tumoral argentina (MAGenTa) [Internet]. Argentina.gob.ar. 2020. Available from: https://www.argentina.gob.ar/ciencia/dnpe/proyectos/medicina-precision/MAGenTa

41. Fernández-Ramires R, Morales-Pison S, Rucatti GG, Echeverría C, San Martín E, Cammarata-Scalisi F, et al. Cancer genetic counseling in Chile: Addressing barriers, confronting challenges, and seizing opportunities in an underserved Latin American Community. Genet Med Open [Internet]. 2024;2(Suppl 2):101898. Available from: https://doi.org/10.1016/j.gimo.2024.101898

42. PAHO/WHO, Pan American Health Organization. Latin America and the Caribbean Code against Cancer [Internet]. 2023. Available from: https://www.paho.org/en/latin-america-and-caribbean-code-against-cancer

43. Argudo-Portal V, Domènech M. The reconfiguration of biobanks in Europe under the BBMRI-ERIC framework: towards global sharing nodes? Life Sci Soc Policy [Internet]. 2020 Oct 1 [cited 2025 Sept 19];16(1):9. Available from: https://doi.org/10.1186/s40504-020-00105-3

44. International Society for Biological and Environmental Repositories (ISBER). Best Practices for Repositories [Internet]. 2025. Report No.: Fifth Edition. Available from: https://www.isber.org/page/BPR

45. Otten LS, Buma AIG, Piet B, ter Heine R, van den Heuvel MM, Retèl VP. Very Early Health Technology Assessment for Potential Predictive Biomarkers in the Treatment of Advanced Non-Small Cell Lung Cancer. PharmacoEconomics - Open [Internet]. 2025;9(3):471–85. Available from: https://doi.org/10.1007/s41669-025-00557-3

46. Ferraro S, Biganzoli EM, Castaldi S, Plebani M. Health Technology Assessment to assess value of biomarkers in the decision-making process. Clin Chem Lab Med [Internet]. 2022;60(5):647–54. Available from: https://doi.org/ 10.1515/cclm-2021-1291

47. Herrero Colomina J, Johnston E, Duffus K, Zaïr ZM, Thistlethwaite F, Krebs M, et al. Real-world experience of Molecular Tumour Boards for clinical decision-making for cancer patients. NPJ Precis Oncol [Internet]. 2025;9:87. Available from: https://doi.org/10.1038/s41698-025-00863-3

48. Anaya JM, Herrán M, Pino LE. Challenges and opportunities for precision medicine in developing nations. Expert Rev Precis Med Drug Dev [Internet]. 2025;10(1):1–15. Avail-

able from: https://doi.org/10.1080/23808993.2025.2505796

49. Horgan D, Ciliberto G, Conte P, Curigliano G, Seijo L, Montuenga LM, et al. Bringing Onco-Innovation to Europe's Healthcare Systems: The Potential of Biomarker Testing, Real World Evidence, Tumour Agnostic Therapies to Empower Personalised Medicine. Cancers [Internet]. 2021;13(3):583. Available from: https://doi.org/10.3390/cancers13030583