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| RESEARCH ARTICLE

Ethical Governance of Bioinformatics and Genomic AI Systems: From Compliance to Institutional Legitimacy

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| ABSTRACT

Bioinformatics and genomic artificial intelligence (AI) systems are increasingly embedded in clinical and organizational decision-making. However, ethical analysis in this area remains dominated by regulatory compliance, privacy protection, and technical control. Although these approaches are necessary, they are analytically insufficient because they do not adequately explain how ethical governance is enacted within organizations, how technological practices mediate governance, or why formally compliant systems may still fail to achieve institutional acceptance. This article develops a conceptual framework through interdisciplinary analysis of biomedical informatics governance scholarship, socio-technical systems theory, organizational theory, and legitimacy theory. Its aim is not merely to synthesize these literatures, but to address an explanatory gap concerning how ethical governance is organizationally produced and how its effectiveness should be evaluated. The proposed Culture–Technology–Ethics–Legitimacy (CTEL) framework links four interdependent domains: organizational culture, bioinformatics technology practices, ethical governance practices, and legitimacy outcomes. The framework makes three conceptual contributions. First, it redefines ethical governance as a cross-level socio-technical process rather than a compliance endpoint. Second, it conceptualizes technology as an ethical mediator through which organizational norms are translated into operational practice. Third, it positions legitimacy as the key downstream outcome of governance and distinguishes scientific, clinical, social, and moral legitimacy as analytically distinct but interacting forms of institutional acceptance. By repositioning legitimacy as the central evaluative outcome of ethical governance, the framework advances biomedical informatics ethics beyond compliance-driven approaches and offers a stronger explanatory account of why some bioinformatics and genomic AI systems become institutionally trusted while others do not. The framework therefore offers a distinct conceptual contribution and a foundation for future empirical investigation.

| KEYWORDS

Bioinformatics; Genomic AI; Ethical governance; Legitimacy; Organizational culture; Biomedical ethics

| ARTICLE INFORMATION

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1. Bioinformatics and Genomic AI in Contemporary Healthcare

Bioinformatics has moved beyond its earlier role as a predominantly research-oriented computational discipline and has become a core component of contemporary healthcare systems. High-throughput sequencing, clinical-grade variant interpretation, and multi-omics analytics now shape diagnosis, prognosis, and therapeutic decision-making across oncology, rare disease, pharmacogenomics, and inherited cardiovascular conditions. In parallel, artificial intelligence (AI) and advanced machine learning have accelerated the development of genomic decision-support systems capable of integrating molecular, phenotypic, and clinical data at scale (Ashley, 2016; Libbrecht & Noble, 2015; Topol, 2019; Vamathevan et al., 2019).

This shift marks more than technical progress. Bioinformatics systems now function as pipeline-based socio-technical infrastructures embedded in institutional governance arrangements, regulatory expectations, and multidisciplinary clinical workflows. Their outputs increasingly shape consequential decisions in patient management and care delivery rather than

remaining confined to research environments (Rehm et al., 2015; Richards et al., 2015). As a result, evaluating these systems can no longer be limited to analytic performance alone.

As these systems become more automated, choices concerning data ingestion, model development, validation thresholds, interpretability, and updating procedures influence not only performance, but also reproducibility, accountability, and trust. Provenance capture, workflow transparency, and auditability therefore become ethically significant rather than merely technical concerns (Goble et al., 2020; Wolstencroft et al., 2013). Decisions made during system design increasingly shape how responsibility, oversight, and justification will later operate in practice.

These developments place new demands on healthcare organizations. Successful implementation depends not only on algorithmic performance, but also on organizational readiness, governance maturity, and confidence in ethical oversight (England, 2023; England, 2024). Ethical governance is therefore not an external constraint on innovation. It is a central determinant of whether bioinformatics and genomic AI systems become trusted, adopted, and sustainably integrated in practice.

At this point, the central analytical problem is no longer simply how such systems work, but how they become governable, trustworthy, and institutionally acceptable. Existing compliance-centered and technically focused accounts do not fully explain that transition. It is this explanatory gap that motivates the present framework.

2. Literature Review

2.1 Ethical Challenges in Bioinformatics and Genomic AI

Ethical challenges in bioinformatics and genomic AI are often grouped under familiar headings such as privacy, bias, and transparency. These categories remain useful, but they can obscure how ethical risk is produced in practice. In healthcare settings, such risks do not arise only from flawed models or insufficient safeguards. They emerge within socio-technical systems in which pipeline architecture, data governance, validation regimes, and organizational norms interact. The literature therefore suggests that the central issues are not isolated technical failures, but governance problems generated, managed, and amplified within institutional settings.

2.2 Genomic Privacy, Security, and Re-identification Risk

A substantial body of literature identifies privacy as one of the most distinctive ethical challenges in genomic data use. Genomic data are highly dimensional, long-lived, and inherently identifying, not only for individual patients but also for biologically related family members. As genomic datasets expand across clinical programs, national biobanks, and cross-institutional collaborations, privacy risks are intensified by linkage, secondary use, and increasingly sophisticated inference techniques (Erlich & Narayanan, 2014; Shabani & Marelli, 2019).

These risks extend across the full data lifecycle, including collection, storage, processing, sharing, and reuse. Ethical vulnerability now extends beyond raw genomic files to derived features, summary statistics, and model parameters. For this reason, privacy in genomic AI is better understood as a dynamic governance problem than as a fixed compliance requirement (Deverka et al., 2020; Shringarpure & Bustamante, 2015).

Recent regulatory and standards-oriented discussions increasingly reflect this shift by treating genomic privacy as an ongoing risk-management issue requiring lifecycle governance, threat modeling, and accountability mechanisms responsive to evolving technological capabilities (Standards & Technology, 2024). In organizational terms, this means that ethical governance must extend beyond consent documentation and access controls to include pipeline-level design choices, provenance mechanisms, stewardship assignments, and institutional responsibility structures.

2.3 Algorithmic Bias, Population Validity, and Fairness in Genomic AI

The literature on genomic AI also emphasizes that algorithmic bias in this domain differs in important ways from bias in many other clinical machine-learning applications. Genomic models are especially sensitive to ancestry representation, population structure, and training-data composition, which can produce systematic disparities in performance across groups. Polygenic risk scores provide a clear example of how technical limitations can become ethical and clinical problems when underrepresented populations receive less reliable predictions (Duncan et al., 2019; Lewis & Vassos, 2020; Martin et al., 2019; Popejoy & Fullerton, 2016).

Although technical responses such as reweighting, transfer learning, and diversification of reference datasets are important, the literature suggests that they do not fully resolve the deeper question of what counts as acceptable evidence, tolerable uncertainty, or fair implementation. Fairness in genomic AI cannot be reduced to a single performance metric; it also involves uncertainty disclosure, clinical communication, and the distribution of benefits and burdens across populations (Obermeyer et al., 2019).

2.4 Reproducibility, Provenance, and Accountability of Bioinformatics Pipelines

Another important strand of literature concerns reproducibility and provenance in bioinformatics pipelines. These are not merely technical issues. As analytic workflows move from research environments into clinical deployment, failures of reproducibility weaken scientific credibility and make clinical accountability more difficult to establish, especially when outputs inform consequential decisions (Begley & Ellis, 2012; Ioannidis, 2014).

Although workflow-centered approaches have improved standardization, persistent challenges remain in ensuring that results are interpretable, auditable, and verifiable over time. Failures in provenance capture or workflow transparency can obscure responsibility, erode clinician confidence, and heighten legal and ethical exposure. In this context, reproducibility and accountability are better understood as core elements of ethical governance rather than as technical quality attributes alone (Cohen-Boulakia et al., 2017; Gruning et al., 2018).

2.5 From Ethical Risk to Adoption Risk: The Centrality of Legitimacy

Taken together, these studies point to a broader issue: ethical adequacy alone does not guarantee adoption. Organizations may implement technically sophisticated and formally compliant pipelines and still encounter clinician resistance, public skepticism, or intensified regulatory concern when governance arrangements are perceived as inadequate. Adoption is shaped not only by technical capability, but also by confidence in ethical oversight, institutional trust, and perceived legitimacy (England, 2023; England, 2024).

The literature therefore suggests that ethical governance should be understood not only as a mechanism for reducing harm, but also as a pathway through which bioinformatics and genomic AI systems acquire scientific, clinical, social, and moral legitimacy. Framing legitimacy as an outcome of ethical governance helps explain why some systems achieve sustained institutional integration while others, despite technical sophistication, fail to gain durable acceptance. It is at this point that compliance-centered approaches begin to show their limits.

2.6 Limits of Compliance-Driven Ethics in Biomedical Informatics

Ethical governance in biomedical informatics has often been framed through regulatory compliance and technical safeguards. These mechanisms are indispensable. They establish baseline protections for genomic and health data and provide formal structures of accountability. However, the literature also shows that they do not adequately explain how ethical governance is enacted in practice, how ethical norms are translated into socio-technical workflows, or why formally compliant systems may still fail to gain trust and sustained use (Floridi et al., 2018; Goodman & Flaxman, 2017; Mittelstadt et al., 2016).

Compliance-oriented frameworks have played an essential role in constraining misuse of sensitive data and institutionalizing practices such as consent, access control, documentation, auditability, and validation. Yet they are typically retrospective and rule-based. As a result, they are less well suited to emergent ethical problems created by rapidly evolving bioinformatics and genomic AI systems. They also offer limited visibility into how ethical norms are interpreted, enacted, or contested within day-to-day practice. Ethical responsibility is therefore often externalized to regulators, review boards, or legal units rather than embedded within the socio-technical processes through which analytic outputs are produced (Mittelstadt et al., 2016).

This limitation is especially clear in genomic AI. Algorithms may satisfy documentation or validation requirements and yet remain opaque to clinicians, difficult to audit in practice, or poorly aligned with clinical judgment and workflow. Compliance alone cannot explain why clinicians may distrust such systems despite regulatory approval, or why public skepticism may persist even in the presence of formal safeguards (Char et al., 2018; Kelly et al., 2019). In this sense, compliance can be understood as a necessary floor of governance, but not as an adequate account of governance itself.

A related issue in the literature is ethical decoupling, namely the coexistence of formal ethical commitments with practices that diverge from those commitments. In biomedical informatics, organizations may publicly endorse transparency, fairness, or patient-centeredness while internal workflows remain organized around efficiency, throughput, or technical optimization with limited ethical scrutiny (Bromley & Powell, 2012). As workflows become more automated and responsibilities more fragmented across data scientists, clinicians, and compliance personnel, ethical governance can become symbolic rather than operational. Compliance-oriented frameworks are poorly equipped to explain this misalignment or to account for how ethical norms are weakened, displaced, or rendered merely performative in practice (Ananny & Crawford, 2018).

The literature on technical fixes points to a further limitation. Interventions such as explainable AI, bias mitigation, and fairness-aware modeling offer valuable tools, but they also risk narrowing ethics to a tractable engineering problem. These approaches cannot determine which disparities matter most ethically, how uncertainty should be communicated, or how competing values should be balanced in practice (Selbst et al., 2019). Without governance processes that integrate ethical reasoning into organizational decision-making, technical interventions may be applied selectively, inconsistently, or merely symbolically. The result is not stronger accountability, but a weaker and more fragile basis for trust.

Taken together, these limitations reveal a gap between ethical adequacy and institutional acceptance. Bioinformatics and genomic AI systems must be accepted by clinicians, patients, administrators, and regulators, and that acceptance depends not

only on technical validity or formal compliance, but also on whether systems are perceived to align with professional norms, societal values, and moral expectations (London, 2019). This gap points to the need for a framework linking organizational culture, bioinformatics technologies, and ethical governance practices to outcomes that matter for real-world deployment, most centrally legitimacy.

3. Methodology

This study adopts a conceptual, theory-building design to develop an explanatory framework for ethical governance in bioinformatics and genomic artificial intelligence (AI). Rather than conducting an empirical investigation, the study uses a structured conceptual analysis to clarify how ethical governance is organizationally produced, technologically mediated, and institutionally evaluated in practice.

The methodological approach is interdisciplinary and draws on four bodies of scholarship: biomedical informatics governance, socio-technical systems theory, organizational theory, and legitimacy theory. These domains were selected because each addresses a distinct dimension of the problem under study. Biomedical informatics governance literature identifies the applied ethical and operational challenges associated with genomic AI. Socio-technical systems theory helps explain how technological design and organizational arrangements interact. Organizational theory provides concepts for understanding how culture, roles, and routines shape governance enactment. Legitimacy theory offers an evaluative lens for examining how governance becomes institutionally consequential.

The conceptual analysis proceeded in three stages. First, literature on bioinformatics and genomic AI was examined to identify recurring ethical challenges, particularly those related to privacy, fairness, reproducibility, accountability, and adoption. Second, literature addressing compliance-based ethics, socio-technical mediation, organizational processes, and institutional legitimacy was examined to identify the explanatory limits of existing approaches. Third, these strands were comparatively interpreted and integrated into a four-domain framework linking organizational culture, bioinformatics technology practices, ethical governance practices, and legitimacy outcomes.

Framework construction followed a principle of analytical differentiation. Organizational culture captures the normative environment in which ethical priorities are interpreted and negotiated. Technology practices capture the operational means through which those priorities are translated into workflows. Ethical governance practices capture the enactment of oversight, responsibility, and accountability. Legitimacy captures whether these arrangements are recognized as appropriate, trustworthy, and acceptable within institutional settings. The proposed ordering of these domains is intended as an explanatory sequence rather than a rigid causal law.

This methodological approach was selected because the study's aim is conceptual clarification and framework development rather than measurement. Accordingly, the paper does not claim empirical validation of the proposed relationships. Its contribution lies in developing a theoretically grounded explanatory architecture for understanding ethical governance in bioinformatics and genomic AI, while providing a foundation for future empirical investigation.

4. Results and Findings: Culture–Technology–Ethics–Legitimacy (CTEL) Framework

The Culture–Technology–Ethics–Legitimacy (CTEL) framework provides a cross-level account of how ethical governance operates in biomedical informatics. Rather than treating ethics as a matter of compliance or technical control alone, CTEL conceptualizes ethical governance as a socio-technical, organizationally mediated, and outcome-oriented process.

CTEL links four interdependent domains: organizational culture, bioinformatics technology practices, ethical governance practices, and legitimacy outcomes. These domains are analytically distinct because each addresses a different dimension of the governance problem. Organizational culture captures the normative environment in which ethical priorities are defined; technology practices capture the operational means through which those priorities are translated into practice; ethical governance practices capture the enactment of oversight, responsibility, and accountability; and legitimacy captures whether these arrangements are recognized as appropriate, trustworthy, and acceptable in institutional settings. Table 1 summarizes the analytical structure of the Culture Technology Ethics Legitimacy framework by distinguishing the conceptual role, explanatory function, governance relevance, and possible empirical indicators of each domain.

Table 1 Analytical Structure of the Culture Technology Ethics Legitimacy Framework

CTEL domain	Conceptual role	Representative elements	Governance relevance
Organizational Culture	Normative and interpretive context shaping how ethical priorities are defined, negotiated, and escalated	Transparency, accountability, risk tolerance, responsible innovation, openness to ethical reflection	Explains why similar technologies may be governed differently across organizations despite comparable formal rules

Bioinformatics Technology Practices	Operational mediation through which organizational values are translated into workflows and system design	Pipeline architecture, validation procedures, provenance capture, interpretability features, documentation standards, update practices	Shows how technical design embeds assumptions about acceptable risk, responsibility, and evidentiary adequacy
Ethical Governance Practices	Organizational enactment of oversight, responsibility, and accountability in routine practice	Oversight routines, accountability structures, stewardship assignments, review procedures, escalation pathways, monitoring mechanisms	Distinguishes enacted governance from symbolic compliance and shows whether ethical concerns are operationally managed
Legitimacy Outcomes	Evaluative consequence indicating whether governance arrangements are recognized as appropriate, trustworthy, and acceptable	Scientific legitimacy, clinical legitimacy, social legitimacy, moral legitimacy	Explains why technically capable and formally compliant systems may still fail to achieve durable institutional acceptance

As shown in Table 1, the four domains are analytically distinct but conceptually interdependent, allowing the framework to explain how ethical governance is organizationally produced, technologically mediated, and institutionally evaluated.
Organizational culture provides the normative and interpretive context within which bioinformatics systems are developed and deployed. Cultural elements such as transparency, accountability, risk tolerance, and responsible innovation shape how ethical issues are prioritized, how uncertainty is managed, and how trade-offs between efficiency and caution are negotiated (Denison, 1990; Schein, 2010). Bioinformatics technologies act as mediating mechanisms between cultural values and ethical practice. Pipeline architectures, validation protocols, provenance mechanisms, and interpretability features translate organizational norms into operational workflows. These technologies are not neutral instruments; they embed assumptions about acceptable risk, transparency, responsibility, and evidentiary adequacy (Floridi et al., 2018; Goble et al., 2020).
Ethical governance practices emerge from the interaction between culture and technological design. Governance is enacted through routine organizational practices rather than being confined to formal policy documents alone. It is through these practices that cultural expectations and technological affordances are aligned, negotiated, and stabilized. Within CTEL, organizational culture is treated as cross-level rather than uniform. At the individual, team, and organizational levels, norms shape how bioinformaticians, clinicians, administrators, and compliance personnel interpret ethical responsibilities and respond to competing priorities. Ethical governance therefore emerges not only from shared norms, but also from negotiation across roles and institutional responsibilities. This helps explain why similar technologies may be governed differently across organizations operating under comparable formal regulatory conditions (Kozlowski & Klein, 2000; Schein, 2010).
The final component of CTEL is legitimacy. Legitimacy refers to whether bioinformatics and genomic AI systems are perceived as appropriate, trustworthy, and acceptable within their institutional environment. The framework identifies four interacting dimensions: scientific legitimacy, reflecting confidence in reproducibility and evidentiary standards; clinical legitimacy, reflecting clinician trust and integration into decision-making; social legitimacy, reflecting public trust and societal acceptance; and moral legitimacy, reflecting alignment with professional and cultural values (Shabani & Marelli, 2019). Framing legitimacy as an outcome of ethical governance helps explain why some systems achieve sustained uptake while others, despite technical sophistication, fail to gain acceptance.
At the same time, legitimacy should not be assumed to be uniformly substantive. Organizations may appear legitimate because they adopt the visible language of ethical governance while leaving problematic practices unchanged. CTEL therefore distinguishes between legitimacy grounded in enacted governance and legitimacy supported mainly by symbolic ethical signaling. This distinction prevents legitimacy from being reduced to a merely reputational achievement.
CTEL also proposes a directional analytical logic. Organizational culture shapes the design and enactment of bioinformatics systems. Bioinformatics technology practices mediate the translation of those norms into operational workflows. Ethical governance then mediates the relationship between these upstream organizational and technological conditions and downstream legitimacy outcomes. This ordering is intended as an explanatory sequence rather than a rigid causal law. In this way, CTEL functions not only as a conceptual synthesis, but also as a framework capable of guiding future empirical inquiry. Figure 1 summarizes these relationships visually.

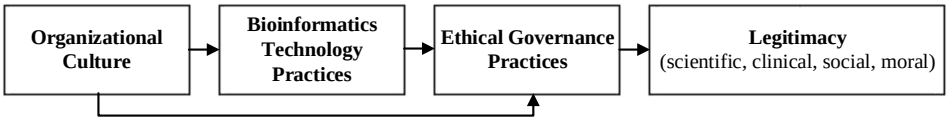

Figure 1. Conceptual representation of the Culture–Technology–Ethics–Legitimacy (CTEL) framework, showing how organizational culture shapes bioinformatics technology practices and ethical governance, and how these governance processes influence legitimacy outcomes

5. Discussion

The present study argues that ethical governance in biomedical informatics should not be treated as a property that can be added to systems through compliance procedures, fairness metrics, or technical documentation alone. Instead, ethical governance is better understood as an organizational accomplishment through which values, responsibilities, and technical arrangements are aligned in practice. This perspective helps explain why technically sophisticated and formally compliant genomic AI systems may still encounter resistance, distrust, or limited uptake. The issue is not simply whether safeguards exist, but whether governance arrangements generate confidence among clinicians, institutions, and wider stakeholders (Char et al., 2018; Kelly et al., 2019; Mittelstadt et al., 2016).

The CTEL framework also clarifies why culture and technology must both be treated as explanatory rather than background variables. Cultural norms shape whether transparency, accountability, and ethical reflection are treated as core operational priorities or as peripheral concerns subordinate to efficiency or speed. Technology, in turn, is one of the principal means through which those commitments are translated into practice. Pipeline design, provenance mechanisms, validation procedures, interpretability features, and output presentation shape what can be seen, justified, audited, and contested. Ethical failures in bioinformatics and genomic AI are therefore often better understood as failures of alignment among organizational culture, technological affordances, and governance practices (Goble et al., 2020; Kozlowski & Klein, 2000; Schein, 2010).

The most distinctive contribution of CTEL lies in its treatment of legitimacy as the key outcome of ethical governance. Existing approaches in biomedical informatics ethics often evaluate systems in terms of compliance, safety, privacy, bias mitigation, or technical accuracy. These remain important, but they do not fully capture whether a system is regarded as appropriate, trustworthy, and acceptable within its institutional environment. The multidimensional view of legitimacy is especially important in this respect. A system may achieve methodological credibility while still failing to gain clinician trust; it may satisfy regulatory expectations while still generating public unease; or it may be clinically useful while remaining morally contested. Ethical adequacy therefore does not automatically translate into institutional acceptance (London, 2019; Suchman, 1995).

These findings have both theoretical and practical implications. Theoretically, CTEL reframes ethics from a compliance-centered problem to a governance process embedded in socio-technical systems, places organizational culture within the explanatory core of ethical performance, and links ethics to adoption, trust, and sustainability through legitimacy. Practically, the framework suggests that governance improvement cannot be limited to policy revision or isolated safeguards. Healthcare organizations must cultivate environments in which ethical concerns can be raised and acted upon, developers must treat interpretability, provenance, validation, and auditability as governance-relevant design features, and institutional leaders must recognize that legitimacy is not a passive by-product of technical success. In practice, such changes may be constrained by time pressures, training demands, and institutional incentives that favor rapid deployment over transparent governance.

Future research should examine how CTEL operates across institutional and national settings, whether the relationship between governance and legitimacy varies across domains such as imaging AI and clinical decision support, and how legitimacy changes over time as systems mature, are contested, or become normalized in practice.

6. Conclusion

Ethical governance in biomedical informatics cannot be understood adequately through compliance alone. This paper argues that ethical governance should instead be understood as a cross-level socio-technical process whose effectiveness is reflected in legitimacy. Through the Culture–Technology–Ethics–Legitimacy framework, ethical governance is repositioned as an organizational process emerging from the interaction of cultural norms, technological design, and enacted governance practices. Bioinformatics and genomic artificial intelligence systems cannot be evaluated adequately through technical adequacy or formal compliance alone; they must also be assessed in terms of whether they are perceived as scientifically credible, clinically trustworthy, socially acceptable, and morally aligned within their institutional settings.

CTEL makes three main contributions. It shifts ethical analysis beyond checklist-based compliance toward governance, places organizational culture at the center of explanation, and positions legitimacy as a multidimensional outcome linking ethical governance to trust, uptake, and sustainability. The framework also has practical implications. Healthcare organizations and system developers must look beyond compliance-oriented responses, attend to the organizational and technical conditions through which confidence is built, and treat legitimacy as a governance objective rather than a passive by-product.

As bioinformatics and genomic AI continue to reshape healthcare, the decisive question will not be only whether these systems work, but whether they are governed in ways that make them worthy of institutional and societal trust. CTEL provides a framework for addressing that question.

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