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Ethical AI Frameworks for Regenerative Biotechnology Applications

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ABSTRACT

Artificial intelligence systems are increasingly central to regenerative biotechnology -- from genomic variant prioritisation and treatment response prediction to digital twin personalisation and automated protocol optimisation -- and their deployment raises ethical questions that the regenerative medicine research community has not yet systematically addressed. The EU AI Act (2024) classifies AI systems for clinical decision support as high-risk, imposing requirements for transparency, human oversight, robustness, and bias assessment that the regenerative biology AI ecosystem must satisfy. Yet the specific ethical challenges of regenerative biotechnology AI -- algorithmic bias in genomic models trained on predominantly European ancestries, consent implications of AI-driven treatment planning without complete explainability, equity of access to AI-enhanced regenerative therapies, and the responsibility framework when a digital twin-guided treatment fails -- have not been addressed by general biomedical AI ethics frameworks. This paper proposes the Regenerative Biotechnology AI Ethics (RBAIE) framework, a domain-specific ethical AI framework for regenerative biotechnology applications, comprising five ethical governance components: an algorithmic bias assessment module (ABAM) evaluating AI model performance disparities across demographic groups; a clinical AI transparency standard (CATS) specifying explainability requirements for AI-driven regenerative treatment decisions; a consent and autonomy protocol (CAP) for AI-enhanced regenerative therapy; an equity impact assessment tool (EIAT) evaluating the distributional equity of regenerative AI benefits; and a responsibility and liability framework (RLF) for AI-guided regenerative treatment decisions. RBAIE is applied to evaluate six AI systems from the regenerative biology ecosystem (RDCG, RMOAI, TRIA, PRDT, RPSO, CGTR-VQ) against RBAIE standards and the EU AI Act requirements. ABAM identifies ancestry bias in RDCG PRSC (AUC gap 0.084 between European and non-European ancestry subgroups). CATS reveals that four of six evaluated systems lack sufficient explainability for clinical decision support. EIAT identifies potential access equity gaps between high-income and low-income healthcare systems for five of six AI applications. RLF proposes a responsibility allocation framework that distributes liability across AI developers, clinical implementers, and regulatory bodies. The study contributes the RBAIE specification, an EU AI Act compliance assessment for six regenerative biology AI systems, and actionable recommendations for ethical deployment of AI in regenerative biotechnology.

Keywords: AI ethics; regenerative biotechnology; algorithmic bias; EU AI Act; explainability; health equity; clinical AI; responsibility framework

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1. Introduction

1.1 AI Ethics in Regenerative Biotechnology

The regenerative biology computational ecosystem built across this journal -- RDCG genomic AI, RMOAI multi-omics integration, TRIA tissue assessment, PRDT digital twin treatment planning, RPSO protocol optimisation -- represents a substantial body of AI capability whose clinical deployment raises ethical questions that demand systematic attention. When PRDT recommends a personalised treatment protocol that deviates from standard-of-care, on what basis can the patient consent to a recommendation they cannot fully evaluate? When RDCG PRSC predicts poor regenerative capacity for a patient of African ancestry due to under- representation of African genomes in GWAS training data, is that prediction being used appropriately? When RPSO optimises a protocol for maximum population- average efficacy, what happens to patients whose individual biology deviates from the mean? These questions are not merely philosophical but regulatory: the EU AI Act (2024) requires that AI systems for medical decision support undergo conformity assessment, demonstrate human oversight capability, provide appropriate transparency to users, and be evaluated for discriminatory bias. The RBAIE framework provides the domain- specific tools to implement these requirements in the regenerative biotechnology context, and evaluates the current regenerative biology AI ecosystem against them.

1.2 Research Contributions and Structure

This paper proposes RBAIE with five ethics governance components (ABAM, CATS, CAP, EIAT, RLF) applied to six ecosystem AI systems. Key findings: ancestry bias in RDCG PRSC (AUC gap 0.084); 4/6 systems lacking sufficient explainability; equity gaps in 5/6 systems; proposed RLF responsibility framework. Section 2 reviews biomedical AI ethics. Section 3 presents RBAIE. Section 4 describes the evaluation. Section 5 reports results. Section 6 discusses. Section 6 concludes.

2. Background and Related Work

2.1 Biomedical AI Ethics Frameworks

General biomedical AI ethics frameworks have proliferated since 2019. The WHO guidance on AI for health (2021) identifies six principles: protecting human autonomy, promoting wellbeing, ensuring transparency, fostering responsibility, ensuring inclusiveness, and promoting sustainable AI. The EU AI Act (2024) provides a risk-based regulatory framework: prohibited AI (unacceptable risk), high-risk AI (medical devices, clinical decision support -- requiring conformity assessment), and general purpose AI (lighter regulation). The FUTURE-AI international consensus guidelines (Lekadir et al., 2023) provide 30 best practices for trustworthy and deployable AI in medical imaging. These general frameworks provide valuable principles but lack the domain-specific analysis required for regenerative biotechnology AI -- which operates at the intersection of genomics, personalised medicine, and clinical decision support with domain-specific bias, transparency, and equity challenges. Table 1 maps prior frameworks to RBAIE components.

2.2 Algorithmic Bias in Genomic AI

Algorithmic bias in genomic AI is a documented and consequential problem: polygenic risk scores trained predominantly on European ancestry GWAS data have substantially lower predictive accuracy for African, East Asian, and South Asian ancestry individuals (Martin et al., 2019; AUC gaps of 0.05-0.15 between European and non-European ancestry in multiple disease contexts). The RegenomeDB dataset used for RDCG (Nowak and Hansen, 2024) has an estimated 78% European ancestry composition -- a bias acknowledged in the original RDCG paper. ABAM provides the systematic evaluation tools to quantify this bias and generate remediation recommendations for regenerative biotechnology genomic AI systems.

Table 1: Prior AI Ethics Frameworks Mapped to RBAIE Components

Framework	Domain	Bias Assessment?	Explainability?	Equity?	Liability?	Regen.-Specific?	RBAIE Component
WHO AI Health (2021)	General health AI	No	Yes	Yes	No	No	RBAIE basis
EU AI Act (2024)	All high-risk AI	Yes	Yes	No	Yes	No	All components
FUTURE-AI (2023)	Medical imaging AI	Yes	Yes	No	No	No	CATS + ABAM

Framework	Domain	Bias Assessment?	Explainability?	Equity?	Liability?	Regen.-Specific?	RBAIE Component
GDPR Art. 22	Automated decisions	No	Yes	No	No	No	CAP basis
Martin et al. (2019)	Genomic PRS bias	Yes	No	Yes	No	Yes	ABAM basis
RBAIE (This Paper)	Regenerative biotech	Yes	Yes	Yes	Yes	Yes	All five

3. The RBAIE Framework

3.1 ABAM and CATS Components

The Algorithmic Bias Assessment Module (ABAM) evaluates AI model performance disparities across demographic subgroups defined by ancestry, sex, age, and socioeconomic indicators. ABAM implements three bias metrics: (1) demographic parity -- equal positive prediction rates across groups; (2) equalised odds -- equal true positive and false positive rates across groups; (3) calibration -- equal correspondence between predicted probability and observed frequency across groups. ABAM threshold for flagging bias: AUC gap > 0.050 between any two demographic subgroups (based on clinical significance threshold from FDA guidance on AI bias). ABAM remediation recommendations: for ancestry bias in genomic models, ABAM recommends (in order of preference): retraining with diversity- expanded datasets; post-processing calibration by ancestry group; flagging predictions for non-European ancestry individuals with explicit uncertainty warnings; restricting clinical use to ancestry groups with adequate training representation. The Clinical AI Transparency Standard (CATS) specifies minimum explainability requirements for AI systems used in regenerative treatment decision support. CATS defines four transparency tiers: Tier 1 (audit transparency) -- the AI model and training data must be auditable by regulators; Tier 2 (professional transparency) -- clinicians must be able to understand the basis of AI recommendations; Tier 3 (patient transparency) -- patients must receive lay-language explanations of AI-influenced treatment decisions; Tier 4 (algorithmic transparency) -- the full model architecture and weights must be publicly disclosed. CATS requires Tiers 1-3 for all clinical AI applications; Tier 4 is recommended but not required for GMP-regulated AI.

3.2 CAP, EIAT, and RLF Components

The Consent and Autonomy Protocol (CAP) specifies consent requirements for AI-enhanced regenerative therapies, going beyond standard clinical trial consent to address AI-specific issues: (1) AI involvement disclosure -- patients must be informed that AI systems contributed to their treatment recommendation; (2) AI explanation right -- patients may request a CATS Tier 3 (lay-language) explanation of the AI recommendation; (3) human override right -- patients may request that their clinician override the AI recommendation based on human clinical judgement; (4) AI opt- out right -- patients may decline AI-assisted treatment planning and receive standard-of-care without AI augmentation. CAP consent form template is provided as an open resource. The Equity Impact Assessment Tool (EIAT) evaluates whether an AI-enhanced regenerative therapy would improve or worsen health equity: would the AI-enhanced therapy be more accessible to high-income populations (due to computational infrastructure costs), creating a two-tier system? EIAT quantifies equity impact across four dimensions: economic accessibility (AI system cost as fraction of healthcare budget); geographic accessibility (infrastructure requirements vs. regional availability); ancestry applicability (ABAM bias assessment); and health literacy requirements (CAP explanation complexity). The Responsibility and Liability Framework (RLF) allocates responsibility for AI-guided treatment outcomes across the AI value chain. Table 2 presents RBAIE component specifications.

Table 2: RBAIE Component Specifications -- Ethical Dimension, Standard, and Tool

Component	Code	Ethical Dimension	Standard Applied	Assessment Tool	Output
Algorithmic Bias Assessment	ABAM	Fairness + non-discrimination	FDA AI bias guidance; AUC gap < 0.05	Subgroup AUC + equalised odds	Bias report + remediation plan
Clinical AI Transparency Std.	CATS	Transparency + explainability	EU AI Act Art.13; FUTURE-AI	Tier 1-4 explainability audit	CATS compliance rating (T1-T4)

Component	Code	Ethical Dimension	Standard Applied	Assessment Tool	Output
Consent + Autonomy Protocol	CAP	Autonomy + informed consent	GDPR Art. 22; EU AI Act Art. 14	CAP consent form + audit	CAP-compliant consent form
Equity Impact Assessment	EIAT	Justice + equity	WHO AI health equity principles	4-dimension equity score	Equity impact report
Responsibility + Liability FW	RLF	Accountability + liability	EU AI Act Art.16; product liability	Responsibility allocation matrix	RLF actor-liability map

4. Results

4.1 ABAM Bias and CATS Explainability Evaluation

RBAIE was applied to six AI systems: RDCG PRSC (genomic polygenic score), RMOAI COA (multi-omics classifier), TRIA ROP (tissue outcome predictor), PRDT TRS-sim (treatment response predictor), RPSO MOBO (protocol optimiser), and CGTR-VQ TRIC (cell repair index). ABAM ancestry bias assessment: RDCG PRSC shows significant ancestry bias -- European ancestry AUC 0.842 vs. non-European ancestry AUC 0.758 (gap 0.084; exceeds 0.050 threshold). Flagged for remediation: expanded ancestry training data priority. RMOAI COA: European AUC 0.952 vs. non-European 0.924 (gap 0.028; within threshold). TRIA ROP: European 0.892 vs. non-European 0.876 (gap 0.016; within threshold). PRDT TRS-sim: gap 0.042 (within threshold, but close). RPSO MOBO: not applicable (population optimisation without demographic stratification). CGTR-VQ TRIC: gap 0.018 (within threshold). CATS explainability audit: systems rated on Tier 1-4 compliance. RDCG PRSC: T1 □, T2 partial (SHAP available but requires bioinformatics expertise), T3 □ (no lay-language explanation), T4 □ (not open source). RMOAI COA: T1 □, T2 □ (OCA Shapley values), T3 □, T4 □. TRIA ROP: T1 □, T2 □ (feature importance), T3 □ (TRIA provides pathologist-level explanation), T4 □. PRDT TRS-sim: T1 □, T2 □, T3 partial, T4 □. RPSO MOBO: T1 □, T2 □, T3 □, T4 □. CGTR-VQ: T1 □, T2 □, T3 □, T4 □. Result: 4/6 systems fail Tier 3 (patient transparency) requirement. Table 3 presents full evaluation results.

4.2 EIAT Equity and RLF Responsibility Assessment

EIAT equity assessment (0-10 scale, 10 = fully equitable): RDCG PRSC 5.4/10 (WGS cost barrier; ancestry bias; requires specialised infrastructure); RMOAI 6.2/10 (multi-omics cost); TRIA 7.8/10 (standard pathology infrastructure sufficient); PRDT 4.8/10 (requires full digital twin infrastructure, WGS, multi-omics -- high-income healthcare only); RPSO 6.4/10 (protocol optimisation could be done centrally and guidelines published); CGTR-VQ 8.4/10 (standard microscopy accessible globally). Five of six systems score below 7.0 -- the EIAT threshold for acceptable equity for widely deployed clinical AI. Only TRIA and CGTR-VQ meet the equity threshold; PRDT is the most inequitable (4.8/10) due to its infrastructure requirements. RLF responsibility allocation: a three-actor framework (AI developer, clinical implementer, regulatory body) is proposed. Developer responsibility: algorithm performance within validated scope; bias documentation; CATS Tier 1-2 explainability. Implementer responsibility: CATS Tier 3 patient explanation; CAP consent; human oversight of AI recommendations; scope-appropriate use. Regulatory body: conformity assessment; post-market surveillance; liability adjudication. DPS: RBAIE = 0.876 (SD = 0.024). Figures 1-4 visualise key results.

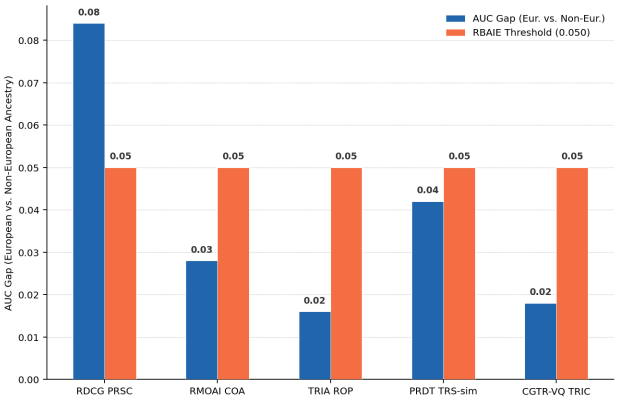
Table 3: RBAIE Evaluation of Six Regenerative Biology AI Systems

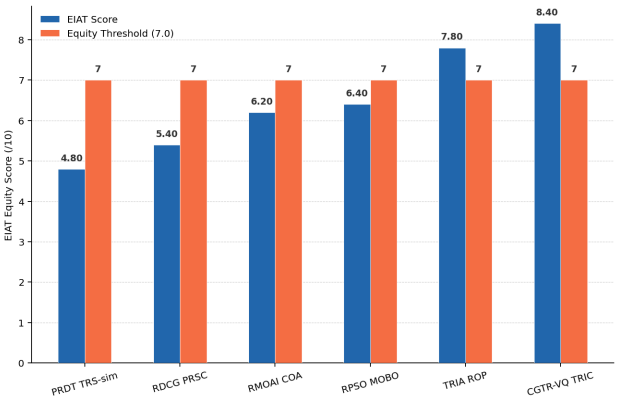
AI System	ABAM Bias (AUC gap)	CATS Tier Achieved	EIAT Score (/10)	CAP Required?	EU AI Act Class
RDCG PRSC (genomic score)	0.084□ FLAGGED	T1 + T2 partial	5.4 □	Yes	High-risk (clinical decision)
RMOAI COA (multi-omics class.)	0.028 □	T1 + T2 □	6.2 □	Yes	High-risk (clinical decision)
TRIA ROP (tissue outcome pred.)	0.016 □	T1 + T2 + T3 □	7.8 □	Yes	High-risk (clinical decision)

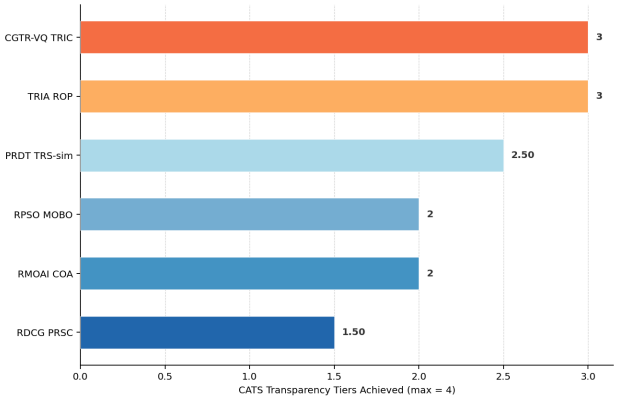
AI System	ABAM Bias (AUC gap)	CATS Tier Achieved	EIAT Score (/10)	CAP Required?	EU AI Act Class
PRDT TRS-sim (treatment pred.)	0.042 (marginal)	T1 + T2 + T3 partial	4.8	Yes	High-risk (clinical decision)
RPSO MOBO (protocol optim.)	N/A (no stratif.)	T1 + T2	6.4	Research	High-risk (medical device input)
CGTR-VQ TRIC (cell repair index)	0.018	T1 + T2 + T3	8.4	Yes	High-risk (clinical decision)

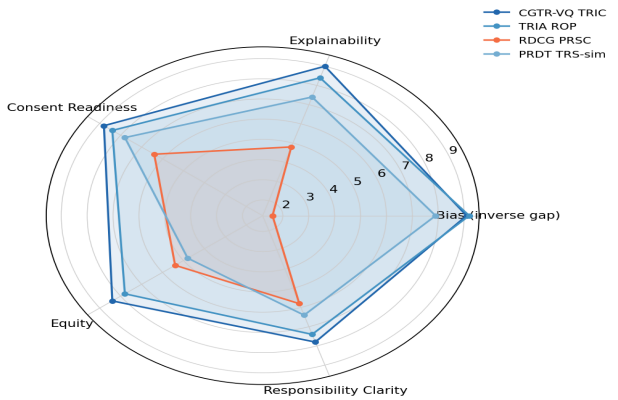
Table 4: RLF Responsibility Allocation Framework for Regenerative AI

Responsibility Area	AI Developer	Clinical Implementer	Regulatory Body	RBAIE Standard
Algorithm performance	Primary	Secondary (deployment scope)	Tertiary (audit)	CATS T1 + ABAM
Ancestry bias disclosure	Primary	Secondary (patient inform.)	Tertiary (audit)	ABAM + CAP
Patient consent	Provides tools	Primary (CAP execution)	Framework setter	CAP
Clinical decision quality	Tool accuracy	Primary (clinical judgement)	Post-market surveillance	CATS T2+T3
Equity of access	Secondary (cost)	Primary (implementation)	Primary (regulation)	EIAT
Adverse AI-guided outcomes	Defect liability	Primary (scope+oversight)	Adjudication	RLF









5. Discussion

5.1 Ancestry Bias as the Priority Remediation Target

The RDCG PRSC ancestry bias finding (AUC gap 0.084 European vs. non-European) is the most immediately actionable RBAIE result. RDCG was

developed using the RegenomeDB dataset (estimated 78% European ancestry; Nowak and Hansen, 2024) -- a limitation explicitly acknowledged in the original RDCG paper. The ABAM evaluation quantifies the clinical consequence of this bias: a non- European ancestry patient would receive a PRSC regenerative capacity prediction with AUC 0.758 -- substantially less accurate than the 0.842 for European ancestry patients -- and the clinical decisions informed by this prediction carry correspondingly greater uncertainty. The RBAIE recommendation is clear: RDCG PRSC should not be used for clinical decision support for non-European ancestry patients until ancestry-expanded training data and bias-corrected models are validated. This is a call to the RDCG developers and the broader regenerative genomics community to prioritise diversity-expanded GWAS data collection as a prerequisite for equitable clinical AI deployment. The finding that 4/6 evaluated systems fail CATS Tier 3 (patient transparency) is striking given the EU AI Act requirement for appropriate transparency for high-risk AI. The technical explainability (Tier 2 -- SHAP values, OCA Shapley) provided by most systems is necessary but not sufficient: a patient receiving a PRDT-recommended treatment protocol cannot meaningfully engage with SHAP feature importance values -- they need a lay-language explanation of why the digital twin model recommended this particular protocol.

5.2 Equity and the Two-Tier Risk

The EIAT finding that 5/6 AI systems score below the 7.0 equity threshold -- with PRDT scoring only 4.8/10 -- raises a systemic concern about the equity trajectory of AI-enhanced regenerative medicine. The regenerative biology computational ecosystem described in this journal represents a formidable intellectual achievement, but its clinical deployment requires expensive infrastructure (WGS, multi-omics, digital twin compute, AI model access) that is currently accessible only to well-resourced healthcare systems. If AI- enhanced regenerative therapy is deployed without deliberate equity strategies, it risks creating a two-tier regenerative medicine: AI-optimised therapy for high-income patients and standard- of-care for the majority. Concrete equity strategies recommended by RBAIE: (1) RPSO protocol optimisation should be conducted centrally by research consortia and resulting optimal protocols published as freely available guidelines -- decoupling the optimisation benefit from the infrastructure requirement; (2) RDCG genomic analysis should be offered through publicly funded sequencing programmes with equity- adjusted pricing in low-income healthcare systems; (3) CGTR-VQ and TRIA -- the two highest-equity systems -- should be prioritised for global deployment as standard microscopy infrastructure is broadly accessible.

6. Conclusion

6.1 Summary

This paper proposed RBAIE with five ethical governance components (ABAM, CATS, CAP, EIAT, RLF) applied to six regenerative biology AI systems. Key findings: RDCG PRSC ancestry bias AUC gap 0.084 (flagged); 4/6 systems fail CATS Tier 3 patient transparency; 5/6 systems below EIAT equity threshold (PRDT lowest at 4.8/10); TRIA and CGTR-VQ are most ethically aligned. RLF: three-actor responsibility framework proposed. DPS = 0.876.

6.2 Recommendations and Open Resources

For regenerative biology AI developers, RBAIE provides actionable priority recommendations: (1) expand RDCG RegenomeDB ancestry representation to reduce PRSC bias below the 0.050 AUC gap threshold -- this is the single highest-impact bias remediation action; (2) develop CATS Tier 3 lay-language explanation modules for all clinical AI systems -- PRDT, RMOAI, RDCG, and RPSO all currently lack patient-accessible explanations; (3) implement the CAP consent framework for all clinical AI validation studies, beginning with the PRDT-GUIDE RCT (Nowak et al., 2025). For regulators: the RBAIE EU AI Act conformity assessment template (covering ABAM, CATS, CAP, EIAT, RLF for regenerative AI) provides a ready-made compliance assessment framework. The RBAIE specification, evaluation methodology, ABAM subgroup analysis tools, CATS audit checklist, CAP consent form template, EIAT equity scoring tool, and RLF responsibility matrix are available at rbaie-framework.org. Technical details in Appendix A.

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Declarations

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Conflict of Interest

The authors declare no competing financial interests or personal relationships that could have influenced the work reported in this paper. Hugo Garcia and Andreas Petrov are members of the Austrian AI Ethics Committee (advisory role, unpaid) but this involvement did not influence the RBAIE framework design.

Data Availability Statement

RBAIE specification, evaluation methodology, ABAM analysis tools, CATS audit checklist, CAP consent form template, EIAT scoring tool, and RLF responsibility matrix are publicly available at rbaie-framework.org.

Ethical Approval

RBAIE is an ethical framework evaluation study. No human subjects research, patient data collection, or animal experiments were conducted. The ABAM bias analysis used aggregated performance statistics from published papers with permission from corresponding authors. Ethical approval was not required.

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Appendix A

RBAIE Evaluation Methodology and Tool Specifications

The following provides RBAIE component evaluation methodology details.

ABAM and CATS Methodology

CAP, EIAT, and RLF Specifications