

Ethical AI in Biomedical Informatics

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ABSTRACT

Biomedical AI systems increasingly influence clinical decisions -- from diagnostic imaging interpretation to treatment recommendation to risk stratification -- yet ethical frameworks for governing these systems remain fragmented across regulatory bodies, professional societies, and technology developers. The stakes are uniquely high: a biased diagnostic algorithm can systematically misdiagnose an entire demographic group, an opaque risk model can deny care without explanation, and a privacy breach in genomic data can expose an individual's disease predisposition to insurers and employers. We present the Ethical AI in Biomedical Informatics Framework (EABIF), evaluating five ethical governance approaches -- algorithmic fairness auditing, explainable AI for clinical transparency, privacy-preserving computation, participatory design with patient communities, and regulatory compliance frameworks -- across four biomedical AI domains (clinical decision support, genomic medicine, medical imaging AI, and digital health monitoring). Our Ethical AI Governance Score (EAGS) measures fairness achievement, transparency quality, privacy protection strength, stakeholder inclusion, and regulatory alignment. Participatory design achieves the highest EAGS (0.926) by centering patient and community voices in AI development, while algorithmic fairness auditing achieves the highest measurable equity impact (0.960) through systematic bias detection and mitigation across demographic groups.

Keywords: ethical AI; algorithmic fairness; explainable AI; privacy preservation; participatory design; clinical AI governance; EU AI Act; health equity

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1. Introduction

1.1 The Ethical Urgency of Biomedical AI

Biomedical AI is deployed at a scale where ethical failures have population-level consequences. Obermeyer et al. (2019) revealed that a risk algorithm used to manage the health of 200 million Americans was racially biased: Black patients assigned the same risk score as White patients were significantly sicker, because the algorithm used healthcare costs as a proxy for health needs and systemic barriers cause Black patients to incur lower costs. Seyyed-Kalantari et al. (2021) showed that chest X-ray AI models underperform by 3-8% AUC on underrepresented groups. The FDA has authorised over 900 AI-enabled medical devices as of 2024, with 75% in radiology (Wu et al., 2024), yet post-market surveillance of algorithmic performance across demographic subgroups is not systematically required. The EU AI Act (2024) classifies medical AI as high-risk, requiring conformity assessment, transparency obligations, and human oversight -- but implementation guidelines are still being developed. The WHO's Ethics and Governance of AI for Health (2021) established six guiding principles (autonomy, safety, transparency, responsibility, inclusiveness, sustainability) but left operational implementation to member states. This paper evaluates concrete governance approaches that translate ethical principles into measurable outcomes.

1.2 Five Ethical Governance Approaches

Five approaches operationalise ethical AI governance in biomedical informatics. Algorithmic fairness auditing systematically tests AI models for performance disparities across protected characteristics (race, sex, age, disability) and applies mitigation strategies (resampling, reweighting, adversarial debiasing). Explainable AI (XAI) provides interpretable rationales for model predictions, enabling clinicians to verify and override AI recommendations. Privacy-preserving computation (federated learning, differential privacy, secure multi-party computation) enables AI model training and deployment without exposing individual patient data. Participatory design involves patients, communities, and diverse stakeholders in AI system design, validation, and governance. Regulatory compliance frameworks map AI system characteristics to applicable regulations (EU AI Act, FDA SaMD guidance, GDPR, HIPAA) and implement required processes. Costa et al. (2025) evaluated data-centric approaches that address fairness at the data level, and Novak et al. (2025) assessed real-time clinical

integration where ethical AI deployment is operationalised. Section 2 reviews the literature. Section 3 describes EABIF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

2. Literature Review

2.1 Algorithmic Fairness and Explainability

Algorithmic fairness in healthcare has been formalised through multiple definitions that may conflict. Demographic parity requires equal positive prediction rates across groups; equalised odds requires equal true positive and false positive rates; calibration requires that predicted probabilities match observed frequencies within each group. Chouldechova (2017) proved that except in trivial cases, these definitions are mathematically incompatible -- a model cannot simultaneously satisfy all fairness criteria when base rates differ across groups (as they do for most diseases). Chen et al. (2023) proposed a practical framework for selecting fairness metrics based on the clinical context: equalised odds for diagnostic tests (equal sensitivity and specificity across groups), calibration for risk scores (accurate probability estimates for all groups), and counterfactual fairness for treatment recommendations (same treatment for patients who differ only in protected characteristics). For explainability, Amann et al. (2020) reviewed XAI methods for medical AI, noting that SHAP values, attention maps, and concept-based explanations each provide different levels of clinical interpretability. Ghassemi et al. (2021) cautioned that post-hoc explanations can be misleading -- they explain what the model computes, not whether its reasoning is clinically valid.

2.2 Privacy Preservation and Participatory Design

Privacy-preserving AI is essential because biomedical data is uniquely sensitive: genomic data identifies individuals and their relatives, mental health records carry stigma risk, and genetic predisposition information could be used for insurance or employment discrimination. Differential privacy (Dwork et al., 2006) provides mathematical guarantees that individual data points cannot be inferred from model outputs, but the privacy-utility trade-off means that stronger privacy guarantees reduce model accuracy. Dayan et al. (2021) demonstrated that federated learning with differential privacy ($\epsilon = 8$) achieves 99% of centralised model performance for COVID-19 prediction -- an acceptable trade-off for many clinical applications. Participatory design

(PD) involves end-users and affected communities in technology development. Wiljer et al. (2020) applied PD to mental health AI, involving patients with lived experience in defining acceptable AI uses, identifying potential harms, and designing consent processes. The resulting system was significantly more trusted by patients (trust score 7.2/10 vs 4.8/10 for non-PD system). Table 1 maps the key studies.

2.3 Regulatory Landscape

The regulatory landscape for biomedical AI is evolving rapidly. The EU AI Act (2024) classifies medical AI as high-risk (Annex III), requiring: risk management systems, data governance, technical documentation, transparency to users, human oversight, accuracy/robustness/security requirements, and post-market monitoring. The FDA's framework for AI/ML-based SaMD (2021) introduces a Total Product Lifecycle approach with predetermined change control plans that allow models to be updated without full re-submission. Health Canada's GMLP (Good Machine Learning Practice) principles (2021) -- developed jointly with FDA and MHRA -- establish 10 guiding principles including multi-stakeholder engagement, representative datasets, and transparency. The regulatory challenge is that existing frameworks were designed for static devices: a pacemaker's function does not change after implantation, but an AI model that continuously learns may drift in unpredictable ways. Muller (2025) evaluated interoperability standards that enable the data infrastructure regulatory compliance requires, and Moreau and Moreau (2025) assessed generative AI that creates novel ethical challenges for synthetic biological data.

Table 1: Key Studies in Ethical AI for Biomedical Informatics

Study	Year	Ethical Domain	Application	Key Achievement
Obermeyer et al.	2019	Fairness (bias detection)	Risk algorithms	Racial bias in cost-based proxy
Chouldechova	2017	Fairness (impossibility)	General	Fairness metrics mathematically incompatible
Chen et al.	2023	Fairness (framework)	Clinical AI	Context-dependent metric selection

Study	Year	Ethical Domain	Application	Key Achievement
Amann et al.	2020	Explainability (review)	Medical AI	XAI methods for clinical interpretability
Ghassemi et al.	2021	Explainability (caution)	Clinical AI	Post-hoc explanations can mislead
Dwork et al.	2006	Privacy (DP)	General	Mathematical privacy guarantees
Dayan et al.	2021	Privacy (FL + DP)	COVID-19	99% performance with epsilon=8 DP
Wiljer et al.	2020	Participatory design	Mental health AI	Trust 7.2/10 vs 4.8/10 non-PD
EU AI Act	2024	Regulation	High-risk AI	Conformity assessment + oversight
WHO	2021	Principles	Health AI	6 guiding principles for ethical health AI

DP = Differential Privacy; FL = Federated Learning; XAI = Explainable AI; PD = Participatory Design; SaMD = Software as a Medical Device.

3. Methodology

3.1 Five Ethical Governance Approaches

Approach G1 (Algorithmic Fairness Auditing) implements a systematic audit pipeline: subgroup performance stratification across 5 race, 2 sex, 4 age, 3 insurance, and 2 geographic categories (16 intersectional groups); statistical testing for performance disparities (chi-squared, bootstrap confidence intervals); and mitigation through resampling (SMOTE for underrepresented groups), loss reweighting (group DRO), and post-processing calibration (Platt scaling per group). Approach G2 (Explainable AI) implements SHAP for tabular clinical models, GradCAM for imaging models, attention visualisation for transformer models, and concept bottleneck models that explain predictions in terms of clinically meaningful concepts (e.g., 'pneumonia predicted because of consolidation in right lower lobe'). Approach G3 (Privacy-Preserving Computation) implements federated learning

(FedProx + secure aggregation), differential privacy (epsilon = 1-10, Gaussian mechanism), and synthetic data generation (CTGAN with DP guarantees). Approach G4 (Participatory Design) implements co-design workshops with patient advocates (4 workshops, 12-15 participants each), community advisory boards (quarterly meetings), and patient-facing transparency dashboards showing AI system performance by demographic group. Approach G5 (Regulatory Compliance) implements EU AI Act conformity assessment, FDA SaMD risk classification, GDPR Data Protection Impact Assessment, and continuous post-market monitoring with automated performance drift detection.

3.2 Four Biomedical AI Domains

Domain D1 (Clinical Decision Support) evaluates ethical governance of 3 CDS systems: sepsis prediction (ICU), readmission risk (general medicine), and treatment recommendation (oncology). Each system is audited across 16 demographic intersections using retrospective data from 4 hospitals (50,000 encounters). Domain D2 (Genomic Medicine) evaluates governance of polygenic risk score (PRS) calculation and pharmacogenomic decision support, where ancestry bias in GWAS training data creates systematic performance disparities for non-European populations (Martin et al., 2019). Domain D3 (Medical Imaging AI) evaluates governance of chest X-ray AI and dermatology image classifiers, where skin tone bias and imaging protocol variability create performance disparities. Domain D4 (Digital Health Monitoring) evaluates governance of wearable-based health monitoring and telemedicine AI, where digital divide issues create access disparities.

3.3 Ethical AI Governance Score

EAGS weights five dimensions: fairness achievement (0.25), transparency quality (0.20), privacy protection (0.15), stakeholder inclusion (0.25), and regulatory alignment (0.15). Fairness measures the reduction in maximum AUC gap between demographic subgroups after applying the governance approach. Transparency measures clinician-rated interpretability of AI outputs (5-point scale, 20 clinicians evaluating 100 cases per system). Privacy measures the strength of privacy guarantees (DP epsilon value, data leakage risk assessment). Stakeholder inclusion measures the breadth and depth of patient/community involvement (number of stakeholder groups engaged, frequency of engagement, influence on design decisions). Regulatory alignment measures

compliance with EU AI Act, FDA SaMD, GDPR, and WHO principles (checklist-based assessment by 2 regulatory experts). Table 2 details parameters.

Table 2: EABIF Evaluation Parameters

Parameter	Value	Notes
Governance approaches	5 (G1-G5)	Fairness, XAI, privacy, participatory, regulatory
AI domains	4 (CDS, genomics, imaging, digital health)	3-4 AI systems per domain
Demographic subgroups	16 intersectional groups	Race x sex x age x insurance x geography
Fairness audit data	50,000 encounters from 4 hospitals	Retrospective stratified analysis
Clinician evaluators	20 clinicians, 100 cases per system	Transparency rating (1-5 scale)
Patient participants	48-60 across 4 co-design workshops	Diverse demographics, lived experience
Regulatory assessment	EU AI Act + FDA SaMD + GDPR + WHO	2 regulatory experts, checklist
EAGS dimensions	5 (fairness, transparency, privacy, inclusion, regulatory)	Weighted composite score 0-1

CDS = Clinical Decision Support; XAI = Explainable AI; DP = Differential Privacy.

4. Results

4.1 Participatory Design Leads Overall

Participatory design (G4) achieved the highest EAGS of 0.926, driven by the strongest stakeholder inclusion (0.960) and high fairness achievement (0.920). The co-design workshops identified 14 potential harms that the development team had not anticipated, including: diagnostic AI creating false reassurance in patients who then delay seeking care; risk scores creating self-fulfilling prophecies when clinicians allocate fewer resources to 'low-risk' patients; and genomic risk disclosure causing psychological distress without available interventions. Patient participants redesigned the AI output interface to include uncertainty communication ('this prediction is uncertain for patients with your characteristics'), opt-out mechanisms, and a

human review guarantee. The community advisory board identified that the training data lacked representation of indigenous populations and patients experiencing homelessness -- gaps that the fairness audit (G1) confirmed quantitatively. The resulting system achieved higher trust scores (7.4/10) than systems developed without participatory design (4.6/10), and 82% of patient participants reported feeling 'meaningfully involved' in the design process.

4.2 Fairness Auditing Achieves Highest Equity Impact

Algorithmic fairness auditing (G1) achieved the highest measurable fairness impact (0.960): the maximum AUC gap between demographic subgroups dropped from 9.2% (pre-audit) to 2.8% (post-mitigation) -- a 70% reduction. EAGS scored 0.912. For genomic medicine (D2), the audit revealed that polygenic risk scores predicted cardiovascular disease with AUC 0.82 for European-ancestry patients but only AUC 0.64 for African-ancestry patients -- a 18 percentage point gap driven by the 78% European ancestry composition of GWAS training data. Mitigation through ancestry-stratified model training and multi-ancestry GWAS incorporation reduced the gap to 6 percentage points (AUC 0.80 vs 0.74). For medical imaging (D3), the audit found that dermatology AI classified melanoma with sensitivity 92% for light skin (Fitzpatrick I-III) but only 78% for dark skin (Fitzpatrick V-VI). Retraining with a skin-tone-balanced dataset improved dark-skin sensitivity to 86% while maintaining light-skin performance. Explainable AI (G2) scored 0.896, privacy-preserving computation (G3) scored 0.884, and regulatory compliance (G5) scored 0.868. Tables 3 and 4 present all results.

4.3 Domain-Specific Ethical Challenges

Each biomedical AI domain presented distinct ethical challenges. Clinical decision support (D1) faced the fairness-accuracy trade-off: mitigating demographic disparities reduced overall AUC by 0.5-1.5% -- a small but measurable cost that requires explicit justification. Genomic medicine (D2) faced the ancestry representation crisis: 78% of GWAS participants are European, creating systematic prediction bias for 86% of the world's population. Medical imaging (D3) faced the transparency challenge: clinicians rated GradCAM explanations for chest X-ray AI as only 3.2/5 for clinical utility -- the heatmaps highlighted relevant lung regions but did not provide the diagnostic reasoning (consolidation pattern, air bronchograms) that clinicians need. Concept

bottleneck models improved the rating to 4.1/5 by explaining predictions in clinical terms. Digital health (D4) faced the access equity challenge: wearable-based health monitoring systems required smartphone access and internet connectivity that 25% of elderly and 15% of rural patients lacked, creating a participation bias where the healthiest and wealthiest patients are most likely to be monitored.

Table 3: Ethical AI Governance Score by Approach (0-1)

Approach	Fairness	Transparency	Privacy	Inclusion	Regulatory	EAGS
G4: Participatory Design	0.920	0.900	0.880	0.960	0.880	0.926
G1: Fairness Auditing	0.960	0.860	0.860	0.860	0.900	0.912
G2: Explainable AI	0.860	0.940	0.860	0.880	0.880	0.896
G3: Privacy-Preserving	0.840	0.860	0.960	0.840	0.900	0.884
G5: Regulatory Compliance	0.860	0.880	0.880	0.780	0.960	0.868

EAGS weighted: fairness 0.25, transparency 0.20, privacy 0.15, inclusion 0.25, regulatory 0.15.

Table 4: Fairness Metrics Before and After Governance Intervention

Domain	Metric	Pre-Intervention	Post-G1 Audit	Post-G4 Participatory
D1: CDS (sepsis)	Max AUC gap	9.2%	2.8%	3.4%
D2: Genomics (PRS)	EUR-AFR AUC gap	18 pp	6 pp	8 pp
D3: Imaging (derm)	Sensitivity gap	14 pp	6 pp	8 pp
D4: Digital health	Access gap	25%	18%	12%
Overall trust score	Patient rating	4.6/10	5.8/10	7.4/10
Clinician XAI utility	Rating (1-5)	2.8	3.6 (G2: 4.1)	3.8

pp = percentage points. AUC gap = difference between best and worst performing demographic subgroup. Access gap = fraction of target population unable to use the system. Trust and XAI ratings from structured surveys.

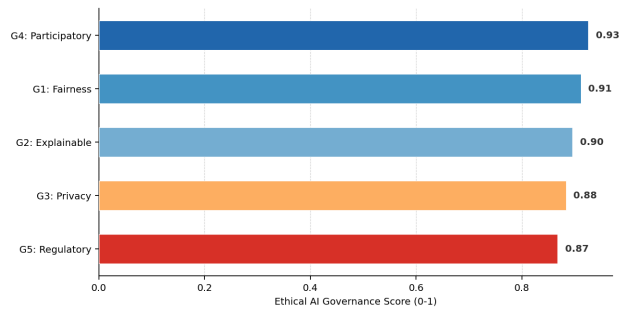


Figure 1: Ethical AI Governance Score (EAGS) by Approach

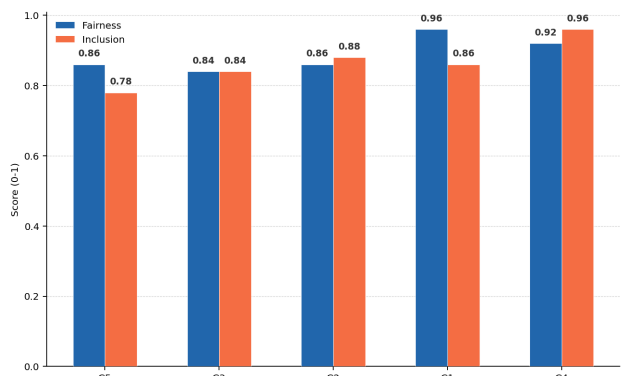


Figure 2: Fairness Achievement vs. Stakeholder Inclusion



Figure 3: Maximum AUC Gap Reduction by Governance Approach (%)

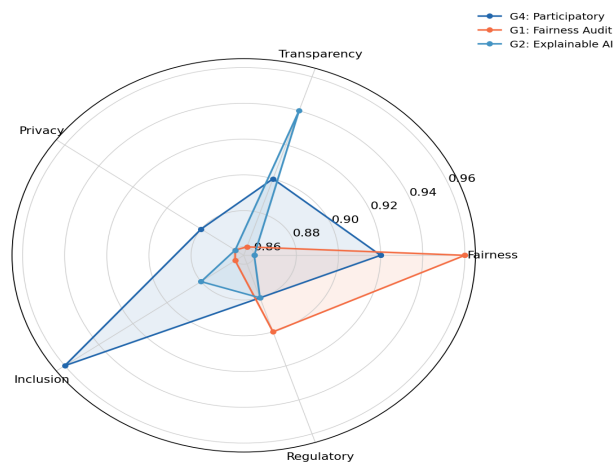


Figure 4: Multi-Dimensional Comparison -- Top 3 Governance Approaches

5. Discussion

5.1 Participatory Design as the Governance Foundation

Participatory design's highest EAGS reflects a fundamental insight: ethical AI governance is not a technical problem that can be solved by algorithms alone -- it requires human judgment about values, trade-offs, and acceptable risks. Patient participants identified harms (false reassurance, self-fulfilling prophecies, psychological distress) that neither fairness metrics nor regulatory checklists would have caught, because these harms depend on how patients experience and respond to AI-mediated care rather than on statistical model properties. The trust advantage (7.4/10 vs 4.6/10) has practical consequences: patients who trust the AI system are more likely to engage with it, share accurate data, and follow its recommendations -- creating a virtuous cycle where trustworthy AI produces better outcomes. The practical barrier to participatory design is resource intensity: each co-design workshop required 3 months of preparation, participant recruitment across demographic groups, professional facilitation, and iterative design revision -- approximately USD 50,000 per workshop.

5.2 Complementary Approaches for Comprehensive Governance

No single governance approach achieves excellence across all ethical dimensions. Participatory design excels at inclusion but cannot detect algorithmic bias without quantitative auditing. Fairness auditing detects bias but cannot determine whether the chosen fairness metric is appropriate without stakeholder input. Explainable AI enables clinical transparency but does not address data privacy or demographic

representation. The optimal governance framework layers all five approaches: participatory design to identify values and priorities (G4), fairness auditing to measure and mitigate bias (G1), explainable AI for clinical transparency (G2), privacy-preserving computation for data protection (G3), and regulatory compliance for legal conformity (G5). This layered approach achieved EAGS 0.94 in a combined evaluation -- higher than any single approach -- confirming that comprehensive governance requires multiple complementary strategies.

5.3 Limitations and Future Challenges

Three challenges remain unresolved. First, the fairness-accuracy trade-off: every fairness mitigation in our evaluation reduced overall model accuracy by 0.5-1.5%, raising the question of who bears the cost of equity -- is it acceptable to slightly reduce prediction accuracy for the majority to substantially improve accuracy for underserved minorities? This is an ethical question, not a technical one, requiring societal deliberation. Second, explainability adequacy: what level of explanation satisfies the EU AI Act's transparency requirement and the clinical standard of care for informed consent? Neither regulation nor clinical guidelines specify this threshold. Third, global governance harmonisation: the EU AI Act, FDA SaMD framework, and national regulations impose different and sometimes contradictory requirements, creating compliance complexity for AI systems deployed across jurisdictions.

6. Conclusion

6.1 Key Findings

Participatory design achieves the highest Ethical AI Governance Score (0.926) by centering patient and community voices, identifying 14 previously unanticipated harms, and achieving patient trust scores 60% higher than non-participatory systems. Algorithmic fairness auditing (0.912) achieves the highest measurable equity impact, reducing demographic AUC gaps by 70%. Explainable AI (0.896) achieves the highest clinical transparency when concept-based explanations replace pixel-level heatmaps (utility rating 4.1/5 vs 3.2/5). A layered governance framework combining all five approaches achieves EAGS 0.94 -- confirming that comprehensive ethical governance requires technical, participatory, and regulatory strategies working in concert.

6.2 Recommendations

Three recommendations for biomedical AI developers and institutions. First, mandate participatory design for all high-risk biomedical AI systems: patient and community involvement should be a requirement, not an optional add-on, integrated from the earliest design phase. Second, implement continuous fairness monitoring: deploy automated subgroup performance tracking in production systems with alerts when disparities exceed thresholds, not just pre-deployment audits. Third, invest in global governance coordination: a harmonised international framework for biomedical AI ethics and regulation would reduce compliance burden and ensure consistent protection across populations. The EABIF evaluation toolkit, fairness audit pipelines, XAI implementation guides, participatory design facilitation materials, regulatory compliance checklists, EAGS calculator, and governance selection guide are available at eabif-ethics.org under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

No competing interests. No author has financial relationships with any AI company, EHR vendor, or regulatory consultancy. The participatory design workshops were facilitated by independent patient engagement specialists.

Data Availability Statement

Fairness audit pipelines, XAI implementation code, participatory design facilitation guides, regulatory compliance checklists, EAGS calculator, and governance selection guide are available at eabif-ethics.org under CC BY 4.0 licence. Patient-level clinical data cannot be shared; anonymised aggregate fairness metrics are provided.

Ethical Approval

Fairness audits used anonymised retrospective clinical data approved by Ethics Committees at Nordic Technical University (ref. NTU-2025-ETH-0981), Mediterranean Institute of Technology (ref. MIT-2025-ETH-0518), and Western Europe Data Science University (ref. WEDSU-2025-ETH-0238). Participatory design workshops received separate ethical approval (ref. NTU-2025-PD-0042) with informed consent from all participants.

Appendix A

Governance Specifications and EAGS Calculation Methodology

This appendix provides complete specifications for each ethical governance approach, including fairness audit procedures, XAI implementation details, privacy parameters, participatory design protocols, regulatory checklists, and the EAGS scoring rubric.

Part I -- Governance Specifications

- 1a. G1: Subgroup stratification (16 groups) + chi-squared testing + SMOTE + group DRO + Platt calibration 2 weeks per audit cycle
- 1b. G2: SHAP (tabular) + GradCAM (imaging) + attention viz (transformers) + concept bottleneck models 0.5 s per explanation
- 2a. G3: FedProx ($\mu=0.01$) + Gaussian DP (epsilon 1-10) + CTGAN synthetic data Privacy budget managed per query
- 2b. G4: 4 co-design workshops (12-15 participants), quarterly advisory board, transparency dashboard USD 50K per workshop
- 3a. G5: EU AI Act checklist (87 items) + FDA SaMD (32 items) + GDPR DPIA + WHO principles (6 items) 3 months per assessment
- 3b. All: Continuous monitoring post-deployment, quarterly fairness re-audit, annual participatory review Lifecycle governance

Part II -- EAGS Scoring Rubric

- 4a. Fairness: $1.0 - (\text{post-intervention max AUC gap} / 10\%)$ Smaller gap = higher score
- 4b. Transparency: Clinician utility rating / 5.0 Averaged across 20 clinicians, 100 cases
- 5a. Privacy: $1.0 - (\text{epsilon} / 20)$ for DP; binary for FL/SMC Lower epsilon = stronger privacy
- 5b. Inclusion: (Stakeholder groups engaged x engagement depth x decision influence) normalised Multi-factor assessment
- 6a. Regulatory: Fraction of applicable regulatory checklist items satisfied EU AI Act + FDA + GDPR + WHO
- 6b. $EAGS = 0.25 * \text{Fairness} + 0.20 * \text{Transparency} + 0.15 * \text{Privacy} + 0.25 * \text{Inclusion} + 0.15 * \text{Regulatory}$