Ethical and Legal Implications - Lung Cancer Classification using Computerized Tomography (CT) Data

This project investigates machine-learning approaches for lung nodule malignancy classification using anonymized Computerized Tomography (CT) data from the LIDC-IDRI dataset. Its purpose is strictly scientific and educational, aiming to evaluate model performance, interpretability, and fairness. The developed models act as decision-support systems, not autonomous diagnostic devices.

Data Protection and Privacy (GDPR): All data are fully anonymized before processing, ensuring compliance with the General Data Protection Regulation (GDPR – EU 2016/679). Processing is carried out under Article 89(1), which permits the use of health data for scientific research when accompanied by technical and organizational safeguards. These include data minimization, pseudonymization, purpose limitation, and secure storage on encrypted institutional servers. No personal identifiers are retained, and no data are transferred outside the European Economic Area. All steps of pre-processing, training, and evaluation are documented to ensure traceability and accountability.

Fairness and Bias Mitigation: Bias in medical imaging datasets can arise from demographic imbalance, scanner heterogeneity, or annotation variability. To mitigate this, the study implements class-balancing strategies, examines per-subgroup metrics, and prioritizes recall (sensitivity) to reduce false negatives, critical in early cancer detection. Evaluation metrics include accuracy, precision, recall, F1-score, and ROC-AUC, interpreted with attention to both clinical relevance and equity. These measures follow the ethical principles of the OECD Framework for Classification of AI Systems (2022) and align with the EU AI Act, which categorizes diagnostic-support tools as high-risk systems requiring transparency and human oversight

Explainability and Accountability: Given the medical domain's demand for interpretability, Explainable AI (XAI) techniques, uch as Grad-CAM and SHAP, are employed to identify relevant visual and radiomic features influencing predictions. All experiments are version-controlled, reproducible, and include detailed documentation of architectures, hyperparameters, and metrics. Clinical accountability remains solely with qualified healthcare professionals; the AI's role is to assist, not to decide.

Regulatory and Ethical Compliance: Any clinical use of this system would require compliance with the Medical Device Regulation (MDR 2017/745) and the EU AI Act, including appropriate documentation, risk management, and post-market oversight. At the research stage, the project aligns with the European Commission's Ethics Guidelines for Trustworthy AI (2019), ensuring lawfulness, fairness, explicability, and technical robustness.This framework bridges current and future regulation: the GDPR and MDR establish today's legal basis, while the EU AI Act sets the emerging governance model for high-risk AI in healthcare, principles already reflected here through transparency, documentation, and human oversight.

Conclusion: The study embodies privacy by design, fairness by evaluation, and explainability by transparency. Through responsible experimentation and strict compliance with ethical and legal standards, it contributes to the development of trustworthy and accountable AI in healthcare research.