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Engineering Predictive AI/ML Pipelines for EGFR-TKI Resistance in NSCLC: A Systematic Review

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Abstract: Resistance to Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitors (TKIs) is a significant challenge in Non-Small Cell Lung Cancer (NSCLC), often resulting in disease progression and reduced survival. Artificial Intelligence (AI) and Machine Learning (ML) models have recently been evaluated for their ability to predict EGFR-TKI resistance and guide treatment. This systematic review assesses studies using AI/ML to forecast EGFR-TKI resistance from radiomics, transcriptomics, clinical, or multi-omics data. A systematic search was conducted across PubMed, Web of Science, and Scopus through March 15, 2025. Studies included applied AI/ML models to predict resistance to EGFR-TKIs in NSCLC. Extracted data included model inputs, performance, and methodological quality, with risk of bias assessed using the PROBAST tool. Ten studies met the inclusion criteria. Models showed promising predictive performance, including radiomics-based models Area Under the Curve (AUC) up to 0.86) and molecular dynamics approaches (accuracy up to 97.5%). Deep learning models stratified patients by mutation status and survival. However, most studies had methodological limitations, including suboptimal measurement of predictors, missing outcomes, lack of external validation, and overfitting. Only two studies had a low or unclear risk of bias across all PROBAST domains. AI/ML models have the potential to predict EGFR-TKI resistance in NSCLC, but methodological heterogeneity and quality issues limit their current clinical utility. Rigorous study design, external validation, and transparent reporting are needed for reliable integration into precision oncology.

Keywords: Non-small cell lung cancer (NSCLC); artificial intelligence (AI); machine learning (ML); EGFR-TKI resistance; predictive modeling.

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1. Introduction

NSCLC represents nearly 85% of lung cancer deaths in the world (Alduais et al., 2023). It is the leading cause of cancer mortality, accounting for approximately 1.8 million deaths annually (Hendriks et al., 2024). As advances in diagnostic and targeted therapies have improved, outcomes for advanced NSCLC remain limited; however, traditional chemotherapy is less effective due to toxicity and poor efficacy (Anand et al., 2022). Precision oncology has improved treatment by detecting actionable genetic drivers of tumor development (Padinharayil et al., 2022).

Of these EGFR mutations, which are exon 19 deletions and exon 21 L858R, up to 50 % of Caucasian patients, and even those with adenocarcinoma and minimal smoking exposure (John et al., 2022). EGFR TKIs developed by Mok et al. (2021) have greatly improved progression-free survival and quality of life in this subgroup. However, most patients develop acquired resistance 9 to 14 months after the first application (Chen et al., 2021). Koulouris et al. (2022) suggested that

resistance is caused by multiple mechanisms: secondary EGFR mutations (such as T790M, C797S), MET or HER2 amplification, bypass pathway activation, epithelial-to-mesenchymal transition, and small cell transformation. Clinically, EGFR-TKI resistance is defined as objective disease progression. It is typically assessed using radiographic criteria, such as Response Evaluation in Solid Tumors version 1.1 (RECIST v1.1), time-to-event endpoints, such as progression-free survival, or molecular evidence of resistance-associated mutations confirmed by next-generation sequencing (Wu et al., 2025). Detection methods for biopsies rely on sampling bias, tumor heterogeneity, and limited accuracy. Radiological imaging is only detectable when biopsies are acquired, which is why current tissue and liquid biopsy detection methods are limited.

AI and ML can address the challenges of modeling large, high-dimensional datasets. In both cases, they can identify complex nonlinear patterns beyond the reach of conventional statistical methods (Wei et al. 2023; Odah, 2024). AI/ML has been shown to have important applications in tumor classification, radiomics, prognostic modeling, treatment response prediction and drug discovery in NSCLC (Ninatti et al., 2020). Interestingly, recent AI/ML pipelines have begun to directly model EGFR-TKI resistance rather than predicting EGFR mutation status solely by combining longitudinal clinical outcomes with resistance-defining molecular events and survival-based endpoints. These methods provide a means of interconnecting genomics, transcriptomics, radiology, proteomics, and clinical variables for predictive modeling of EGFR-TKI resistance (Avci et al., 2024). A control-based learning model of support vector machines, random forests and gradient boosting has been applied to genomic predictors (Barragán-Montero et al. 2022) and deep learning, which extracts resistant characteristics from imaging and pathology, is applied to deep learning models. Other multi-omics approaches that use molecular and clinical data are also useful for risk stratification (Alharbi and Vakanski, 2023).

While these advances have facilitated clinical translation, they are limited by difficulties with data quality, model interpretation, external validation, and population generalizability (Nagarajaiah et al., 2024). There is a wide variety of data sources, modeling practices, and validation methods available, and several models exhibit strong in silico performance but lack external validation and are not available for real-world practice. This synthesis of current evidence needs to clarify methodological trends, identify limitations, and guide future development of clinically reliable AI/ML software (Martínez García and Hernández-Lemus, 2022).

2. Materials and Methods

The present review was carried out according to the PRISMA framework (Page et al., 2021; Urrútia and Bonfill, 2010). In this regard, it aimed to provide an exhaustive analysis of available information on the application of artificial intelligence (AI) and machine learning algorithms for predicting resistance to EGFR inhibitors.

2.1. Design and Search Strategy

Two independent researchers, in January 2025 and March 2025, searched PubMed, Scopus and Web of Science for research papers published from 2020 to March 30, 2025. The MeSH terms and free-text keywords related to NSCLC, EGFR inhibitors, AI, ML and drug resistance were used. To ensure full reproducibility in accordance with PRISMA 2020 guidelines, reproducible search strategies were applied to the specific database as described below. All searches focused on English-language, peer-reviewed journal articles on human subjects published between 1 January 2020 and 30 March 2023.

PubMed (MEDLINE) search strategy:

((“Non-Small Cell Lung Cancer”[MeSH Terms] OR “NSCLC”[Title/Abstract] OR “Lung Neoplasms”[MeSH Terms]) AND (“Epidermal Growth Factor Receptor Inhibitors”[MeSH Terms] OR “EGFR-TKI”[Title/Abstract] OR “Tyrosine Kinase Inhibitors”[Title/Abstract]) AND (“Artificial Intelligence”[MeSH Terms] OR “Machine Learning”[MeSH Terms] OR “Deep Learning”[Title/Abstract] OR “Predictive Model”[Title/Abstract]) AND (“Drug Resistance, Neoplasm”[MeSH Terms] OR “Resistance”[Title/Abstract] OR “Acquired Resistance”[Title/Abstract])) Filters applied: Humans, English, Publication dates from 01/01/2020 to 03/30/2025.

Scopus search strategy:

(TITLE-ABS-KEY(“non-small cell lung cancer” OR NSCLC OR ”lung neoplasms”) AND TITLE-ABS-KEY(“EGFR inhibitor” OR “EGFR-TKI” OR “tyrosine kinase inhibitor”) AND TITLE-ABS-KEY(“artificial intelligence” OR “machine learning” OR “deep learning” OR “predictive model*”) AND TITLE-ABS-KEY(“resistance” OR “drug resistance”)) AND (LIMIT-TO(DOCTYPE, “ar”)) AND (LIMIT-TO(LANGUAGE, “English”)) AND (PUBYEAR > 2019 AND PUBYEAR < 2026).**

Web of Science Core Collection search strategy:

TS=(“non-small cell lung cancer” OR NSCLC OR “lung neoplasms”) AND TS=(“EGFR inhibitor” OR “EGFR-TKI” OR “tyrosine kinase inhibitor”) AND TS=(“artificial intelligence” OR “machine learning” OR “deep learning” OR “predictive model*”) AND TS=(“resistance” OR “drug resistance”) Refined by: Document Types = Article; Languages = English; Timespan = 2020–2025.**

Boolean operators were used to refine search specificity, and the reference lists of all included studies were manually screened to identify additional eligible articles not captured by the electronic search. The complete search process, including the execution dates and database-specific query syntax, was prospectively defined and registered. The review protocol was registered in PROSPERO (CRD420251013123).

2.2. Selection of Studies and Eligibility Criteria

To include high-quality, relevant studies, certain eligibility criteria were used. The following studies were selected for inclusion.

(1) studies on EGFR inhibitor resistance prediction based on AI or ML models in adult NSCLC patients.

(2) published in an original peer-reviewed English-language journal.

(3) studies that had sufficient information on the accuracy of ML/AI models in predicting drug resistance.

(4) published between 2020 and March 30, 2025.

For clarity within this review, EGFR TKI resistance was specifically identified by the occurrence of either of the following events: (a) radiographic evidence of progressive disease per RECIST v1.1 or similar criteria, (b) time-to-event end points (e.g., PFS or TTF), or (c) molecular documentation of acquired resistance mechanisms. Examples of molecular confirmation include detection of EGFR T790M or C797S mutations using NGS or other validated molecular methods.

There were four distinct inclusion/exclusion factors: (1) all in-vitro or animal models, (2) those lacking data related to AI/ML and/or those which were unavailable from studies, (3) those involving no EGFR treatment, and (4) non-specific studies addressing the prediction of drug resistance in NSCLC.

Those studies focusing on the predictive value of EGFR mutation or genotype without direct linkage to clinical/molecular resistance-related outcomes, except when the mutation status was explicitly modeled as a surrogate or intermediary endpoint for EGFR-TKI resistance, were excluded.

2.3. Screening and Data Extraction

Two independent reviewers were involved in screening for studies and extracting data. In cases where a discrepancy arose regarding a study's inclusion/exclusion at any stage of review, a consensus was achieved by the two independent reviewers or through consultation with a third reviewer.

A pilot study was conducted before the actual screening began. The pilot study was a calibration exercise that involved having two independent reviewers screen an initial random sample of abstracts from potentially eligible studies to determine whether they would interpret the inclusion/exclusion criteria consistently and apply them similarly throughout the screening process. Screening occurred in three stages. First, titles and abstracts were analyzed to narrow the pool of eligible studies. Second, full-text articles were checked for inclusion and exclusion. Further criteria for eligible articles were applied to the reference lists of the included articles.

Cohen's kappa (κ) was used to measure inter-rater agreement, indicating significant agreement at title and abstract screening ($\kappa = 0.82$) and near-perfect agreement at full text screening ($\kappa = 0.88$). Both reviewers independently extracted data in duplicate using a standard extraction form. Discussion and consensus were used to resolve any disagreements that arose during screening or data extraction. Where consensus was not reached, a third reviewer made the final decision.

Data were extracted using a standard format that identified all participating studies: authors, year, and country, using a structured form that defined study characteristics, EGFR inhibitor type, AI/ML methods, supervised learning, and deep learning. These measures were compared for accuracy, sensitivity, specificity, and AUC, along with information on the clinical, genomic, and radiologic input data and the training or validation process used in model development.

2.4. Quality Assessment of the Included Studies and Risk of Bias (ROB).

The quality and validity of the research were evaluated using two different criteria, PROBAST and GRADE. ProBAST assessed bias risk across four domains: participants, predictors, outcomes and analysis. Two reviewers independently graded each area. If a disagreement was resolved between two reviewers, they argued, or another reviewer passed it to another reviewer. A measure of assessment was sample representativeness, predictor-outcome independence, clarity of outcome definitions and methodological strength in analysis, such as cross-validation, handling missing data, and safeguards against overfitting or data leakage.

Overall, ROB was categorized by the ROB 2 tool in Table 1 as high (+), low (-), or unclear (!) based on the highest-risk domain area. A test of accuracy in evidence was then applied to the certainty of the evidence. By examining PROBAST-informed bias, inconsistency, indirectness, imprecision, and publication bias, the quality of evidence was defined as high, moderate, low, or very low.

Given the diverse populations, study designs, data types (imaging, genomic, clinical), and AI/ML approaches, a narrative synthesis was employed. The study clusters were grouped by algorithm type, data source, and EGFR mutation class. Low-bias, high-quality studies were prioritized, while high-risk studies were considered low-bias. Therefore, this approach enabled a structured, clinically relevant understanding of AI/ML performance in predicting EGFR-TKI resistance in NSCLC.

3. Results

3.1. Literature Search Results

The follow-up of PRISMA guidelines, based on a systematic, transparent search in PubMed, Scopus, and Web of Science, yielded 3,684 records related to AI/ML prediction of EGFR-TKI resistance in NSCLC. By removing 24 duplicates, 3,660 articles were reviewed by title and abstract, and 3,640 were dismissed because they lacked relevance to the prediction of resistance to EGFR-TKI, were not modeled in AI/ML, were not designed in human format or did not reveal resistance-related results. Twenty full-text articles were assessed, and ten were excluded specifically for the following reasons: outcome

not related to EGFR-TKI resistance or progression endpoints (n = 4). In vitro or animal-only studies without clinical validation (n = 3). Lack of reporting of AI/ML model architecture, inputs, or performance metrics to allow methodological assessment (n = 3). The remaining studies met all inclusion criteria and were included in the final qualitative synthesis.

Fig. 1 shows a completed PRISMA 2020 flow chart demonstrating the identification and screening of the study, eligibility assessment, and inclusion, with explicit exclusion criteria at the full-text stage. The PRISMA flow diagram depicts all selection steps, as shown in Fig. 1.

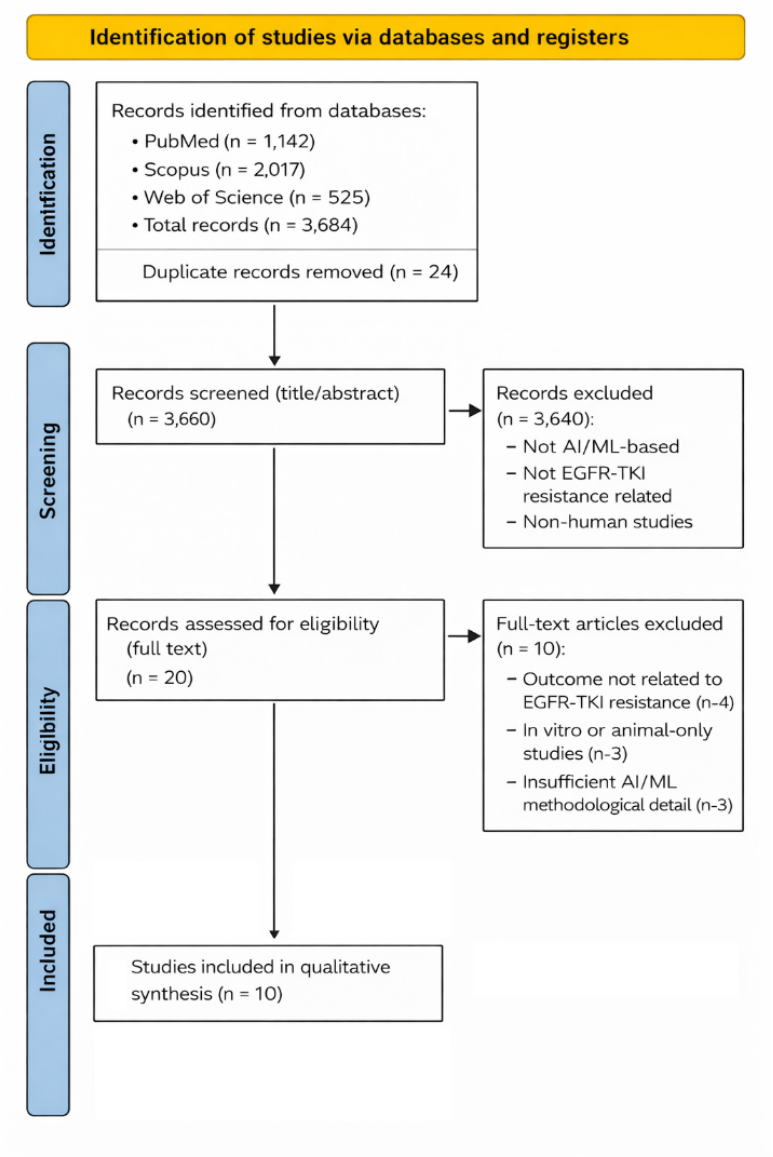

Fig. 1. PRISMA flow diagram: study identification and selection

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

3.2. Characteristics of the Included Studies

Table 1 summarizes the main features of the 10 research studies published from 2020 to 2025, demonstrating the growth of an emerging market for using AI/ML to predict how well patients will respond to, and/or become resistant to, EGFR-targeted therapies for lung cancer.

The studies described below all utilize several computer-based analytical tools (e.g., multi-omics analysis, radiomics, deep learning, molecular dynamics simulations) to enhance understanding of how prognostic biomarkers can be used to forecast patient drug responses and mechanisms of drug resistance.

To ensure the clinical utility and novelty of this review of existing literature, studies that did not specifically model EGFR-TKI resistance, treatment failure, or surrogate measures of resistance were systematically excluded. Studies that modeled EGFR mutation status alone were also excluded, as each study indicated that mutation status was directly associated with resistance, treatment failure, or progression-related outcomes.

These studies developed predictive models for endpoints such as time-to-progression (TTP), progression-free survival (PFS), and EGFR-TKI resistance, using independent datasets, clinical data, computed tomography (CT) and magnetic

resonance imaging (MRI) images, gene-expression profiling, and molecular simulation analyses. The predictive performance of these models was assessed by computing their receiver operating characteristic curve area under the curve (AUC), accuracy, sensitivity, specificity, and C-index values. Overall, these studies demonstrate how AI/ML are being applied in precision medicine.

The review article shows that AI/ML can be an important resource for identifying biomarkers and clinical predictors to advance personalized therapy in both non-small cell lung cancer (NSCLC) and EGFR-mutant NSCLC.

The reviewed articles employed various AI/ML techniques, including deep learning, random forests, support vector machines (SVMs), artificial neural networks, and radiomics.

One of the researchers employed a multi-omics integration method by combining genomic, transcriptomic, proteomic, and radiologic information (CT and MRI) to develop higher-dimensional predictive models based upon large amounts of data. This was consistent with another trend toward developing more sophisticated models of cancer.

Most studies have demonstrated clinical evidence supporting the use of third-generation EGFR tyrosine kinase inhibitors (TKIs), especially osimertinib, specifically for T790M mutations in resistant EGFR TKI-treated patients. The other authors who wrote about earlier inhibitors like gefitinib and erlotinib were able to discuss their mechanisms of action. Specifically, these authors described the mechanisms behind resistance in patients harboring the L858R mutation, those undergoing a small-cell transformation, and those exhibiting multiple mutations.

Each of the three mechanisms is an example of the biological heterogeneity found in NSCLC. Therefore, each of the three will require individualized or personalized predictive tools developed from large datasets.

Supplementary Table 1 summarizes some of the models, performance metrics, and the data sets from which they were derived. It also describes what is currently known regarding the development of AI/ML-based predictive models for drug resistance in NSCLC.

Table 1. Characteristics of included studies in the systematic review

Author(s)	Year	Objective	Country	EGFR-TKI Studied
Zhou et al.	2024	Developed a 22-gene multi-omics signature using machine learning to predict gefitinib resistance in lung adenocarcinoma.	China	Gefitinib
Sinha et al.	2024	Applied single-cell transcriptomics and computational modeling to predict resistance to EGFR-TKIs across cancers.	USA	EGFR-TKIs (general)
Lu et al.	2024	Utilized radiomics and ML to predict acquired EGFR T790M mutation post EGFR-TKI therapy in NSCLC patients.	China	EGFR-TKIs (general)
Liang et al.	2023	Designed a neural network-based clinical decision support system to predict EGFR-TKI efficacy using NGS data.	China	EGFR-TKIs (general)
Wang et al.	2022	Employed AI models on whole-lung imaging to predict EGFR genotypes and therapeutic responses in a multi-cohort study.	China	EGFR-TKIs (general)
Qureshi et al.	2022	Developed a personalized drug response prediction model using ML tailored to lung cancer EGFR mutation profiles.	Pakistan	EGFR-TKIs (general)
Yuan et al.	2021	Used computational analysis to identify DNA methylation sites linked to EGFR-TKI responsive genes in lung cancer.	Taiwan	EGFR-TKIs (general)
Trivizakis et al.	2023	Created a deep radio transcriptomics model combining imaging and transcriptomic data to subtype NSCLC cases.	Greece	EGFR-TKIs (general)
Tang et al.	2024	Implemented CT radiomics with machine learning to predict progression-free survival in EGFR-T790M positive NSCLC.	China	Osimertinib (EGFR-TKI)
Song et al.	2020	Developed a deep learning-based model to predict EGFR-TKI response and PFS in stage IV EGFR-mutant NSCLC patients.	China	Gefitinib, Erlotinib (First-gen EGFR-TKIs)

3.3. Comparative Analysis of AI/ML Model Performance

In a systematic review of EGFR inhibitors across the model and multiple models, he identified different approaches and compared their performance across key metrics to provide a comprehensive overview of these models.

The types of input data and validation methods used to train the AI/ML models varied widely depending on the algorithms, input data types, and validation methods, as illustrated in Fig. 2. Table 2 presents the types of input data and validation methods used.

There were significant differences among studies regarding their data source(s), whether single center or multiple centers, how they defined endpoints such as radiographic progression, molecular resistance and/or survival; how features were preprocessed prior to modeling and how each study validated its results.

These differences make it difficult to compare the model's overall performance directly among studies, caution should be used when comparing model performance based upon performance metrics and when a model appears to have better-than-average performance.

As shown in Table 2, the best-performing molecular dynamics simulation model for predicting gefitinib/erlotinib response was the XGBoost Classifier, with an accuracy of 97.5%. Random forest classifiers reliably separated the EGFR-TKI-resistant samples in cross-validation at 54%. Wang et al. (2022) indicated that stacked ensemble methods are most effective at developing training/testing protocols in large multi-cohort analyses. Stacked Ensemble achieved 93% in the training dataset and 83% in the test set. However, many of these studies did not perform external validations using independent datasets collected from other sites/institutions.

Many of the studies relied solely on internal cross-validation for estimating accuracy. Internal cross-validation may yield inflated estimates of a model's performance due to residual data leakage, homogeneity within the study sample, and/or uncontrolled confounders.

Table 2. Comparative accuracy of AI/ML models in predicting EGFR-TKI resistance in NSCLC

Model Type	Accuracy (%)	Sample Size	Validation Method	Study
XGBoost Classifier	97.5%	120	External validation	(Qureshi et al., 2022)
Random Forest	97.3%	273	5-fold cross-validation	(Tang et al., 2024)
Stacked Ensemble	93.0% (training); 83.0% (testing)	18,232	Multi-cohort	(Wang et al., 2022)
ANN-based CDSS	82.0%	351	External validation	(Liang et al., 2023)
Radiomics + Clinical	78.0–89.0%	183	Internal validation	(Lu et al., 2024)
Deep Learning (BigBiGAN)	Not directly reported	Stage IV EGFR+ NSCLC	Multi-cohort validation	(Song et al., 2020)
Group LASSO/LASSO	Not directly reported	Lung cancer cell lines	Functional validation	(Yuan et al., 2021)
Elastic Net (PERCEPTION)	Not directly reported	Single-cell transcriptomics	Leave-one-out cross-validation	(Sinha et al., 2024)

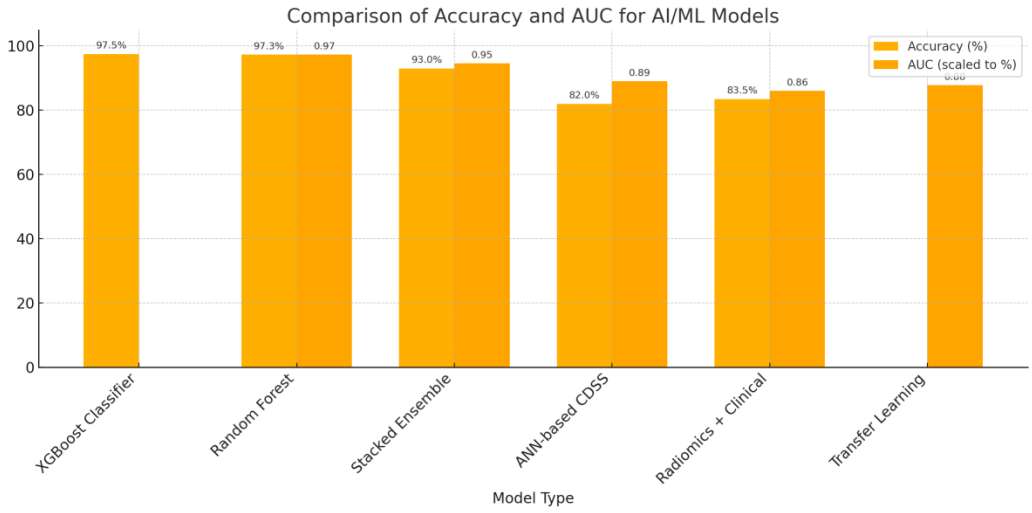

Fig. 2. Comparison of model performance

In each model using pre-trained ImageNet architectures, transfer learning models with AUC values of 0.925 ± 0.04 for histology subtype prediction and 0.831 ± 0.09 for molecular subtype prediction showed excellent results. Although there was some variation in the external validation performance, there were high internal validation (AUC = 0.973) and 'low external validations' (AUC = 0.817), demonstrating that robust verification practices are necessary.

The input data type and primary outcome varied in many of the studies. Table 4 reveals the results for those studies.

The reorganization of input data and the multi-omics (genomic, transcriptomic) approach to imaging radiomics to CT images indicate the range of approaches to predicting EGFR-TKI resistance. These models, based on molecular dynamics simulations and multi-omics data, were significantly better than their radiomics counterparts and provided good performance metrics, though still a bit below the norm. To provide a global overview of model performance across studies, Fig. 3 presents comparisons for each AI and ML model.

Table 3. AUC performance of AI/ML models for EGFR-TKI resistance prediction

Model Type	AUC	Target Prediction	Study
Transfer Learning (ImageNet)	0.925 ± 0.04	Histology subtypes	(Trivizakis et al., 2023)
Transfer Learning (ImageNet)	0.831 ± 0.09	Molecular subtypes	(Trivizakis et al., 2023)
Random Forest	0.973 (internal); 0.817 (external)	EGFR-TKI resistance	(Tang et al., 2024)
Deep Learning (FAIS)	0.748–0.813	EGFR genotype	(Wang et al., 2022)
ANN	0.89	EGFR-TKI efficacy	(Liang et al., 2023)
Radiomics + ML	0.86	T790M mutation	(Lu et al., 2024)
Multi-ML models	0.897–0.995	EGFR/ALK prediction	(Zhou et al., 2024)

During this comprehensive comparison, we report that many models improve accuracy in XGBoost and Random Forest, while others make gains in other metrics, such as AUC, Transfer Learning, C-index, and Stepwise Regression, as seen in Fig. 4. The variability in the reported metrics across studies shows a need for the standardization of reporting of model performance to provide meaningful comparisons. Comparison of these AI/ML models suggests their potential to predict EGFR inhibition resistance in NSCLC patients. However, this heterogeneity in study design, validation approaches, and reported metrics requires appropriate interpretation and strong external validation before clinical implementation, and care must be taken in the context of study design and validation methods.

Table 4. Model types and input data for EGFR-TKI resistance prediction

Model Type	Input Data	Primary Outcome	Study
Random Forest / LASSO / Gradient Boosting	Multi-omics (mRNA; scRNA-seq; SNP)	Gefitinib resistance signature	(Zhou et al., 2024)
Elastic Net Regularization	Single-cell transcriptomics	TKI response prediction	(Sinha et al., 2024)
Decision Tree / KNN / LR / NB / RF / SVM / XGBoost	Radiomics + clinical data	T790M mutation status	(Lu et al., 2024)
Artificial Neural Network	Clinical + NGS data	EGFR-TKI efficacy	(Liang et al., 2023)
Deep Learning (FAIS)	Whole-lung CT images	EGFR genotype prediction	(Wang et al., 2022)
XGBoost Classifier	Molecular dynamics simulations	Gefitinib/Erlotinib response	(Qureshi et al., 2022)
Group LASSO / LASSO Regression	Methylation sites	EGFR inhibitor sensitivity	(Yuan et al., 2021)
Transfer Learning (ImageNet)	CT images + transcriptomics	Molecular/histology subtypes	(Trivizakis et al., 2023)
Random Forest / SVM / Stepwise / LASSO	Radiomics + clinical factors	Progression-free survival	(Tang et al., 2024)
BigBiGAN + LASSO Cox	CT images (deep semantic features)	Survival stratification	(Song et al., 2020)

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3.4. ROB and Quality Assessment in Included Studies

3.4.1. Methodology quality

The measures analyzed with the PROBAST instrument primarily assess the risk of bias across predictors, outcomes, and analyses among participants. Results are summarized in Supplementary Table 2, with score details in the appendix. On a wider scale, clinical and molecular features were essential to research. Important biomarkers, such as EGFR and tumor mutation burden, could improve prognosis and treatment response. These biomarkers pose an important challenge for AI-driven oncology research, particularly given the need to combine molecular and clinical data.

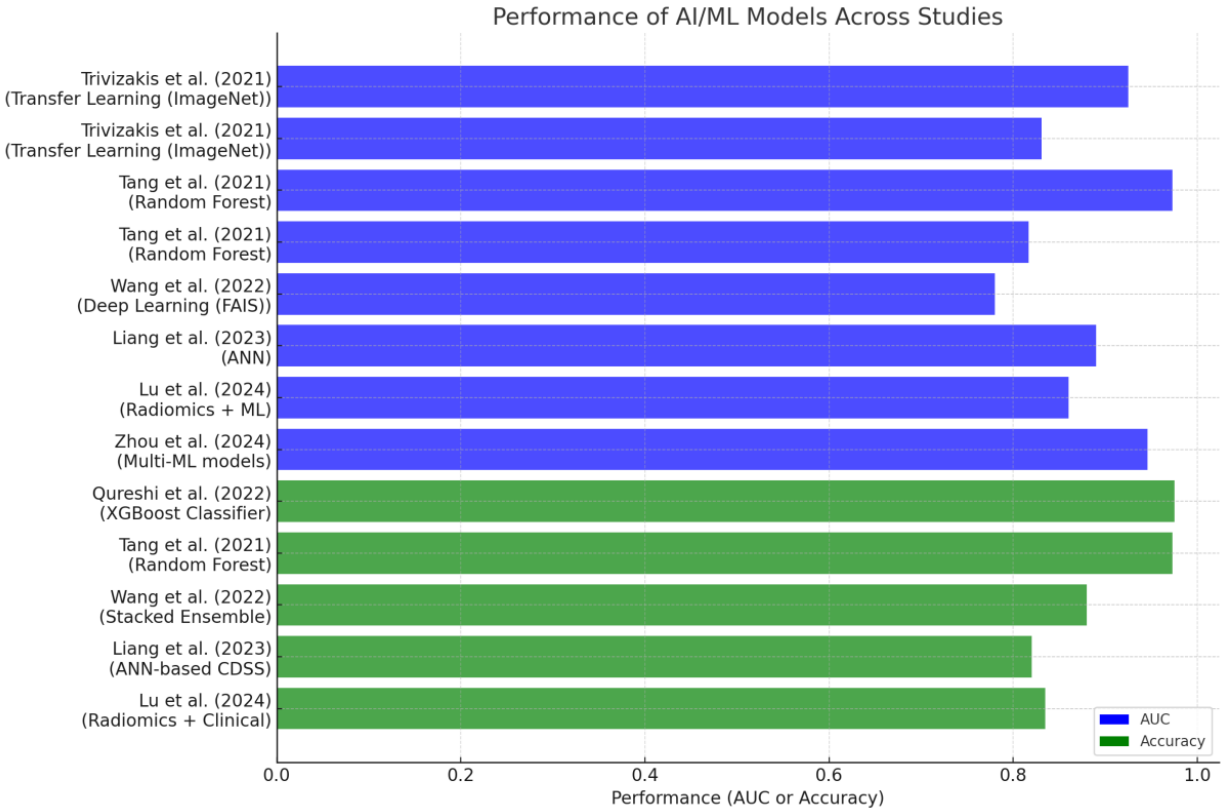

Fig. 3. Comparative performance of machine learning models using different feature selection techniques

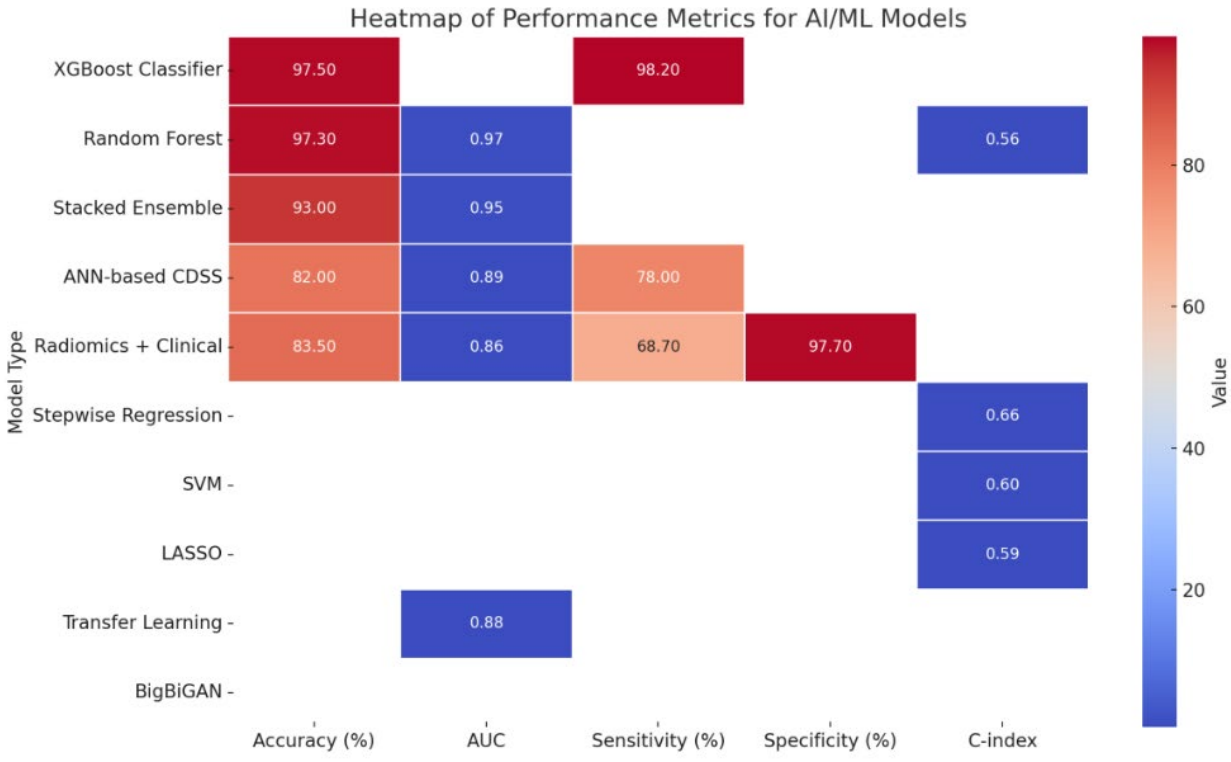

Fig. 4. Heatmap performance metrics comparison across different AI/ML models

3.4.2. ROB assessment

While the methodological quality was generally excellent, several studies showed a significant risk of bias, particularly in the predictors and analysis domains of PROBAST (Supplementary Table 2).

In general, inadequate external validation, inconsistent endpoint operationalization, and heterogeneous preprocessing workflows were the most frequent contributors to elevated bias risk across the included studies. These factors directly affect the interpretation of model performance and weaken confidence in clinical translatability.

Zhou et al. (2024), Yuan et al. (2021), and Lu et al. (2024) reported weak randomization and cross-validation issues, as well as limited accuracy and generalized their predictive models. Nguyen et al. (2024), Wang et al. (2022), and Song et al. (2020) reported that the likelihood of bias across all domains was consistently low across levels, sample sizes, real-world multi-center data, and prospective validation. This methodological strength substantially strengthens the robustness and clinical application of their models.

3.4.3. Domain-specific risk of bias

Participants: Some studies faced challenges with representation due to limited sample sizes or limited demographic diversity. For instance, in the studies by Zhou et al. (2024) and Trivizakis et al. (2023), geographically limited or low-variance samples reduced their external validity and applicability.

Predictors: Overfitting and data leakage were prevalent. The articles by Zhou et al. (2024) and Sinha et al. (2024) failed to implement appropriate controls to ensure that the model was not detecting noise rather than a false pattern in the clinical context. These issues compromise the effectiveness of the prediction.

Results: The articles by Zhou et al. (2024) and Trivizakis et al. (2023) did not adhere to standardization and blinding procedures and hence were at high risk of introducing subjectivity. The papers by Wang et al. (2022) and Song et al. (2020) compared their outcomes and improved reliability.

Analysis: Among all the areas, this one exhibited the highest variability. Most studies reported performance metrics but lacked measures to address class imbalance or to conduct external validation. For example, the study by Wang et al. (2022) considered external validation using a potential multi-cohort approach. Additionally, some studies used techniques such as SMOTE and ADASYN to create a balanced dataset. Furthermore, inappropriate missing data handling.

3.4.4. Applicability and clinical utility

Many other studies, including those from Yuan et al. (2021), Trivizakis et al. (2023), and Zhou et al. (2024), did not lend themselves to a clinical application due to the unavailability of a wide range of predictive factors outside of clinical settings or being based on small, localized groups. As well, even though some models may demonstrate good internal validity metrics (i.e., AUC > 0.9). The lack of standardized methodologies for collecting the model's input variables (e.g., resistance testing data) and output values (e.g., the specific type of drug resistance test) significantly impedes the ability to reliably reproduce model results externally. For this reason, predictions generated by these models should be considered as preliminary indications of potential clinical applicability rather than definitive assessments of their clinical accuracy. Wang et al. (2022) and Song et al. (2020) used biomarkers relevant to patient care, including EGFR mutation status and surrogate biomarkers of tumor burden. These biomarkers provided more direct links to models with greater clinical relevance, helping inform decisions in the clinic. Additionally, both Wang et al. (2022) and Song et al. (2020) were found to have high clinical utility, as indicated by lower ROB scores in larger, multicenter studies and rigorous validation processes. Liang et al. (2023) stated that although high-performing AI/ML models may achieve an AUC < 0.85, further external validation will be required before implementing them in a medical setting. In contrast, the studies by Lu et al. (2024), Yuan et al. (2021), and Zhou et al. (2024) were deemed unlikely to be sufficiently useful for clinical practice and would likely require substantial additional development before application in a laboratory setting. The ProBAST evaluation emphasizes the need for improved study designs, standardized resistance-assessment methods, and extensive external validation to ensure the safe and reliable clinical translation of AI/ML models designed to predict EGFR-TKI resistance in patients with NSCLC.

3.5. Main Findings of AI and ML Models for Predicting EGFR Inhibitor Resistance in NSCLC

The diversity of computational techniques, from genetic signatures to radiomics, single-cell transcriptomics, and even molecular dynamics simulations, has been instrumental in improving EGFR-TKI resistance prediction. Such tools reveal critical information about the tumor heterogeneity, its response to medication, and the acquired resistance. All study groups utilized radiographic progression, survival time-to-event measures, or the molecular appearance of resistance-mediating genotypes to operationalize the resistance outcome, allowing modeling of clinically relevant EGFR-TKI resistance rather than merely making an indirect prediction of its genetic origin. The resistance gene to gefitinib was identified using multi-omics modeling, including mRNA expression and immune microenvironment characteristics, according to reports by Zhou et al. (2024). Even though such techniques show promise, they still require translation and a way to resolve multimodal data processing challenges. High-resolution data about the resistant subpopulation can be provided by Sinha et al. (2024) and the PERCEPTION pipeline. However, the computing costs associated with developing and using these technologies are extremely high.

AI-enabled personalized medicine has gained the capacity to predict. Qureshi et al. (2022) used molecular dynamics simulations and ML to accurately predict patient-specific EGFR-TKI response, achieving a 97.5% success rate. Meanwhile,

Liang et al. (2023) used artificial neural networks to predict NGS and clinical data with 82% success rate. The predictive capacity of both measures appears impressive, yet both studies still require longer cross-cohort validation. Overall, the existing evidence strongly suggests that the use of AI and ML to predict EGFR-TKI resistance is a revolutionary trend that may transform NSCLC treatment in the coming years. Yet there is much to achieve before implementing this technique clinically.

4. Discussion

AI and ML have become a cornerstone in NSCLC studies, moving from a clinically-oriented perspective to computational modeling in high dimensions. For stratification of patients based on their prediction of resistance, the most common models include random forests, SVMs, and LASSO regression. Feature scaling is the biggest technological challenge in machine learning. Indeed, modeling is limited due to variability in imaging, sequencing and preprocessing of data. The techniques that can be used include transfer learning and domain adaptation. Yet, feature space remains significantly different between the samples. Interpretation of the model is important as well. Though deep learning models achieve the highest accuracy, a lack of explanation requires XAI methods such as SHAP, LIME, and attention mechanisms to justify predictions at the function level.

The quality of validation varies across models. Namely, the vast majority of the models lack randomization, the number of participants is insufficient, and external validation has not been conducted. The methodologies in Qureshi et al. 2022 and Liang et al. 2023 prove to be the strongest techniques, providing maximum transferability during cross-validation and multi-cohort benchmarking. Indeed, current models are just a step forward from those of the modern era. So, Zhou et al. (2024) have developed a multi-omics gene signature using Random Forests and LASSO to identify 22 genes resistant to gefitinib treatment. Despite difficulties in interpretation, developing a pipeline is possible and useful. In addition, the PERCEPTION algorithm proposed by Sinha et al. (2024 identifies resistant subpopulations within single-cell RNA-sequencing data via elastic net learning, but is incomprehensible to the general user.

Radiomics remains a prominent AI application. In this study, Lu et al. (2024) and Tang et al. (2024) analyze the clinical significance of imaging features for T790M mutation status and progression-free survival, respectively. These multimodal models demonstrate the utility of feature fusion but highlight ongoing problems with standardizing imaging protocols and the deficient interpretation of radiomic signatures. AI is also transforming personalized medicine. Qureshi et al. (2022) combined MD simulations with XGBoost to predict EGFR-TKI response with 97.5% accuracy, demonstrating the feasibility of simulation-generated ML despite its computational complexity. Liang et al. (2023) used NGS and clinical data models and performed well in this model despite cohort variability, identifying an important need for cross-population validation and transfer learning, despite the relative accuracy of ANN models.

Potential arises from deep learning's ability to dynamically generate representations. Song et al. (2020) used a BigBiGAN to extract semantic features from CT scans and predict progression-free survival (PFS). In addition, this allows for an easier learning representation through more personal experiences rather than each individual radiomic. However, GANs have limitations due to their opacity, high data requirements, limited clinical interpretability and limited resolvability. Approaches that integrate multi-omics data, such as those described by Trivizakis et al. (2023), offer clear performance benefits; however, they pose significant technical challenges in handling missing data, ensuring computational scalability, and designing integration strategies. Regardless of these advancements, there exist system-wide impediments to translation. As most studies will not require access to prospective data, they are generally non-generalizable. Furthermore, a lack of standardization in data acquisition and preprocessing exists, which is detrimental to reproducibility. Explainability remains a necessary component because clinicians cannot rely on models that do not defend or validate their actions. Lastly, deployment will also be required to optimize in terms of model compression, federated learning and scale-up.

Future research should employ a range of methodologies to advance the clinical and engineering development of AI/ML pipelines for predicting EGFR-TKI resistance. First, the resistance endpoints should be defined by standards accepted in clinical practice (e.g., RECIST v1.1-defined progression; clear time-to-event thresholds), so that results can be compared across groups. Second, investigators should strive to encourage pre-registration for future prospective studies and increase transparency of their study protocols to eliminate the chance of biased selective reporting of results and disparate analytical methods. Third, all AI/ML studies should follow current guidelines (e.g., TRIPOD-AI for reporting transparent models and PROBAST-AI for assessing risk of bias). Fourth, validation of robustness in the heterogeneous data environment will require external validation from the institution, the imaging platform, and the sequencing pipeline. Finally, in addition to a complete separation of training, testing, and validation datasets (with explicit protection against performance estimation bias due to "data leakage" during feature selection and model tuning).

To advance the development of AI and machine learning (ML) technologies for non-small cell lung cancer (NSCLC), many researchers have found that using AI and ML together is challenging. However, their ultimate goal is to provide better methods, improve consistency of the datasets being used, enhance the interpretation of results from these studies, and allow them to be translated into clinical use.

5. Conclusion

This systematic review emphasized the transformative potential of machine learning and artificial intelligence for personalized therapy for non-small cell lung cancer (NSCLC). This could be used in conjunction with genetic information, radiomics, deep learning, and multi-omics platforms, leading to better predictions of drug resistance, therapy response, and cancer relapse. The advantages of these changes include the potential to revolutionize medical decision-making through individual patient care and best-practice approaches.

Some obstacles must be overcome before these technologies can be widely adopted. This is one of the major barriers to data standardization, as imaging and clinical data may not fully characterize findings. While this is still an issue, understanding the reasoning behind the prediction is still a significant challenge. Clinicians need to understand the purpose of predictions so they can trust them and decide how to interpret them. These more computational, intelligence-driven AI algorithms will increasingly be drawn to faster, more targeted oncology procedures. Although there are different pieces of evidence from this work, as discussed here. These studies showed that other studies had a consistently low risk of bias and the highest quality score. However, a few cases were found to have methodological flaws, including small sample sizes, moderate to high risk of bias, and heterogeneous data collection methods. Although ML and AI models are very promising, the variability in study quality underscores the need for caution when interpreting results and for further research. It is good to see AI and ML in the future of cancer treatment, but it is difficult to win over the public. The greatest challenge in future research will be to realize their full potential in high-quality prospective studies with rigorous methodology, thereby achieving the best results. In contrast, to maintain widespread acceptance in the medical literature, data standardization and the comprehensibility of AI models are needed. With increased computing resources, advanced algorithms, and value-oriented research, the success of AI and ML will lead to their effective application in personalized cancer therapy, especially in NSCLC.

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Author Contributions

Faris and Mohanad contributed to the conceptualization, methodology, and investigation. Alaa and Rania handled data curation and formal analysis. Faris prepared the original draft, which was reviewed and edited by Mohanad and Alaa. Mohanad provided supervision and validation. Project administration was handled by Mohanad, Alaa, and Rania. All authors have read and agreed to the published version of the manuscript.

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