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Artificial intelligence in lung cancer pathology: tool or paradigm shift?

Abstract

Over the past decade, artificial intelligence (AI) in lung cancer pathology has advanced from proof-of-concept image classifiers to clinically consequential systems that support histological subtyping, mutation inference from hematoxylin and eosin (H&E) whole-slide images, quantification of spatial and immune biomarkers, prognostic modelling, and laboratory workflow redesign. A 2025 prospective silent-trial deployment of a fine-tuned pathology foundation model for *EGFR* detection in lung adenocarcinoma showed that an AI-assisted workflow can reduce the number of rapid molecular tests required by a clinically meaningful margin while preserving current clinical-standard performance, providing the strongest real-world evidence so far that computational pathology can alter diagnostic sequencing in routine practice. At the same time, external-validation reviews continue to document methodological fragility, restricted datasets, and inconsistent generalization across scanners, stains, institutions, and specimen types. In this Review, we examine whether AI in lung cancer pathology should still be regarded as a sophisticated diagnostic accessory or whether it constitutes an emerging paradigm shift. Drawing on landmark deep-learning studies, recent systematic and narrative reviews, prognostic and predictive signatures, and the rise of pathology foundation models, we argue that AI has exceeded the definition of an ancillary tool, because it is beginning to change what can be inferred from a histological slide—transforming routine tissue into a high-dimensional computational substrate. However, AI has not yet become a mature paradigm: external validation, governance, interoperability, and workforce integration remain insufficient. Pulmonary pathology in 2026 is therefore best understood as a transitional paradigm in active formation, in which AI-augmented expertise—rather than autonomous algorithms—defines the most realistic and responsible near-term trajectory.

Keywords: artificial intelligence, lung cancer, computational pathology, whole-slide imaging, foundation models, EGFR, biomarker discovery, tumor microenvironment, pathologist-in-the-loop, digital pathology.

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Panel: Search strategy and selection criteria

We searched PubMed, Scopus, and Web of Science from Jan 1, 2018, to Jan 31, 2026, using combinations of the terms (“lung cancer” OR “lung adenocarcinoma” OR “non-small-cell lung cancer” OR “small-cell lung cancer”) AND (“artificial intelligence” OR “deep learning” OR “machine learning” OR “computational pathology” OR “foundation model” OR “whole-slide imaging”) AND (“pathology” OR “histopathology” OR “biomarker” OR “EGFR” OR “mutation prediction” OR “prognosis” OR “immunotherapy response”).

We hand-searched reference lists of identified reviews, the 2025 Nature Medicine real-world deployment study of a fine-tuned pathology foundation model for EGFR detection, and landmark papers in Nature Medicine, npj Precision Oncology, Modern Pathology, EBioMedicine, and The Lancet Digital Health. We prioritised peer-reviewed articles in English reporting external or prospective validation, large multi-institutional cohorts, or conceptual advances relevant to pulmonary pathology.

We included narrative and systematic reviews, meta-analyses, landmark original studies, and real-world deployment evidence. Preprints and single-institution retrospective studies without external validation were considered only when conceptually pivotal. The final reference list reflects a purposive, rather than exhaustive, selection consistent with the Review format of The Lancet Oncology.

Introduction

Lung cancer remains the leading cause of cancer death worldwide, and pulmonary pathology sits at an unusually demanding intersection of diagnostic complexity, tissue scarcity, and biomarker dependence. Contemporary treatment decisions in non-small-cell lung cancer (NSCLC) require integration of histological subtype, molecular status, and immune context, often derived from small biopsies or cytology-rich specimens. Into this ecosystem, artificial intelligence (AI) has arrived with unusual velocity: in less than a decade the field has moved from convolutional neural networks trained on whole-slide images (WSIs) to large-scale pathology foundation models deployed prospectively in real clinical practice.[1–3]

The most consequential recent development is conceptual as much as technical. Computational pathology has begun to redefine what information can be inferred from a routine histological slide. The WSI increasingly functions not merely as a substrate for qualitative visual interpretation, but as a high-dimensional data object from which latent phenotypes, treatment-relevant biomarkers, and operational signals can be extracted.[2,4] In lung cancer, where tissue is often limited and clinical decisions are increasingly biomarker-dependent, this reframing has immediate translational implications.

Earlier work in lung digital pathology established the conceptual basis for AI-assisted classification, grading, and biomarker analysis, and anticipated the regulatory, reimbursement, and deployment challenges that still define the field.[2] More recent literature has sharpened the translational question. A 2024 systematic scoping review of externally validated pathology AI models for lung cancer diagnosis concluded that, despite encouraging performance, the evidence base remained methodologically fragile and clinically under-validated.[1] By contrast, the 2025 real-world deployment of a fine-tuned pathology foundation model for *EGFR* detection in lung adenocarcinoma demonstrated that prospective clinical integration is now technically feasible and operationally meaningful.[3] The coexistence of these realities—impressive innovation alongside incomplete generalization—frames the central tension of this Review.

In this Review we examine whether AI in lung cancer pathology should still be regarded as a sophisticated tool or whether it constitutes an emerging paradigm shift. Our emphasis is deliberately on AI as a technology and its relationship to diagnostic workflow, rather than on disease biology. We argue that AI in pulmonary pathology is best understood as a transitional paradigm: already more than an ancillary instrument, but not yet a fully stabilized clinical paradigm.

Why pulmonary pathology is a distinctive testbed for AI

Pulmonary pathology combines complex morphology, heterogeneous tissue quality, and a continuous clinical demand for integrated morphological and molecular interpretation.[2,5,6] Whole-slide imaging digitizes this complexity, while deep learning, weakly supervised learning, and increasingly foundation-model-based approaches enable feature extraction at scales that exceed unaided human visual cognition.[2–4] In lung cancer this is not merely a faster microscope; it represents a shift from descriptive histopathology to inferential and quantified histopathology, in which the slide becomes a computational substrate.

Pulmonary pathology is routinely asked to perform several roles simultaneously: identify tumor, classify subtype, estimate grade or architectural pattern, preserve tissue, coordinate molecular testing, and contextualist immune or spatial biomarkers. AI is attractive in this environment not only because it can automate repetitive tasks, but because it may uncover latent relations between tissue architecture and genotype, prognosis, or treatment response.[2-7] Lung pathology is therefore not simply a use case for AI; it is a field in which AI exposes the possibility that morphology encodes more biological and therapeutic information than conventional reading workflows can routinely extract.

From classification engines to computational phenotyping systems

The first major wave of lung pathology AI focused on classification. Landmark work by Coudray and colleagues showed that convolutional neural networks trained on WSIs could distinguish lung adenocarcinoma, squamous cell carcinoma, and non-tumor tissue, and suggested that selected molecular alterations might be predicted directly from H&E sections.[4] This was a pivotal moment because it introduced the idea that histology might carry sufficient signal not only for tumor typing, but also for genotype-proximate inference.

Subsequent work expanded from fully supervised pipelines to weakly supervised and annotation-efficient approaches, reducing dependence on exhaustive region-level labels and improving scalability for gigapixel images.[2,4,5] As the field matured, the emphasis moved beyond simple tumor detection toward broader forms of computational phenotyping. Contemporary reviews describe lung computational pathology as encompassing subtyping, grading, prognostic signatures, prediction of adjuvant chemotherapy benefit, quantification of immune features such as PD-L1–related patterns, and multi-task platforms built on shared digital pathology infrastructure.[2,6,7]

The conceptual importance of this transition is substantial. A tool automates a predefined human task. A computational phenotyping system, by contrast, extends the range of questions that can be asked of a slide. Once AI begins to infer biological states, approximate molecular status, or derive prognostic patterns that are not explicitly visible as standard histological criteria, the system is no longer just reproducing the pathologist's workflow. It is augmenting and, in some respects, reorganizing the informational architecture of pathology.

Histological subtyping, grading, and morphometric standardization

One of the most mature uses of AI in lung pathology remains histological discrimination and subtype refinement. The 2024 external-validation scoping review showed that pathology AI models for lung cancer have most often been applied to malignant-versus-non-malignant classification, growth-pattern assessment, and adenocarcinoma-versus-squamous subtyping, with reported AUCs spanning a wide range across settings.[1] These figures show that many classification tasks are now technically tractable.

Translational interpretation of these results nevertheless requires caution. The same review found high or unclear risk of bias in every included study in at least one QUADAS-AI-P domain, with recurrent concerns about retrospective design, restricted datasets, non-representative populations, and inadequate specification of real-world operating thresholds.[1] Strong classification metrics do not automatically imply clinical robustness. The most useful current role for AI in subtyping and grading may therefore lie in standardization and second-read support, particularly in settings where diagnostic variability, workload, or subspecialty access are limiting factors.

Grading and architectural-pattern analysis may ultimately prove more transformative than binary subtype classification. Recent reviews emphasis that AI can operationalist grading systems with greater consistency, generate reproducible morphometric signatures, and link histological organization to prognosis and treatment effect in ways that conventional visual scoring only partially captures.[2,6,7] This is one of the clearest points at which AI begins to challenge the boundary between assistance and paradigm change: the slide is no longer only being read, it is being computationally modelled.

Molecular inference from routine histology

Among all applications in pulmonary pathology, molecular inference from H&E WSIs is arguably the strongest candidate for paradigm-shifting significance. If a routine histological slide can be used to prioritize or approximate actionable genomic information, AI changes not merely the efficiency of pathology, but the sequence and logic of diagnostic work itself.

The possibility was foreshadowed by early deep-learning studies linking whole-slide morphology to mutations in NSCLC.[4] A 2024 systematic review and meta-analysis specifically examined deep-learning prediction of oncogenic driver alterations from histopathology in lung cancer, confirming sustained interest in mutation inference across adenocarcinoma, squamous, and small-cell contexts.[5] Although the extracted evidence remains heterogeneous, the review is important

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because it consolidates a field moving from isolated demonstrations toward a recognizable translational domain.

The most compelling advance to date is the 2025 Nature Medicine study on real-world deployment of a fine-tuned pathology foundation model for *EGFR* biomarker detection.[3] Investigators assembled an international lung adenocarcinoma cohort comprising several thousand digital slides and reported strong internal and external discrimination, followed by prospective silent-trial performance that remained robust in routine practice.[3] Crucially, the AI-assisted workflow reduced the number of rapid molecular tests required by a clinically meaningful margin while preserving current clinical-standard performance.[3] This is not simply faster pattern recognition; it is evidence that AI can act as a molecular triage layer, conserving tissue, shortening time to actionable information, and altering how pathology and molecular testing are coordinated.

Even here, the implications must be framed carefully. AI does not replace sequencing and should not be treated as a universal surrogate for molecular diagnostics. Its emerging role is to prioritize, triage, enrich, and accelerate. The most defensible near-term model is therefore not substitution but workflow redesign, in which AI outputs support faster and more tissue-efficient allocation of confirmatory molecular resources.[3,5]

Spatial biomarkers and the tumor microenvironment

A second paradigm-relevant domain is the analysis of spatial tissue organization. Traditional histopathology has always interpreted architecture, but AI can quantify spatial relations among tumor cells, stromal compartments, immune infiltrates, and other microenvironmental patterns at scales and levels of reproducibility that are difficult to sustain manually.[2,6] In lung cancer this matters because therapeutic response—particularly to immune checkpoint inhibitors—depends not only on tumor-intrinsic alterations but also on tissue ecology.

Reviews of lung digital pathology have highlighted a growing interest in AI-based quantification of PD-L1–associated features, tumor-infiltrating lymphocytes, and other microenvironmental biomarkers.[2,6] More recent work extends this logic to computationally derived spatial biomarkers that seek to predict prognosis, response to immune checkpoint inhibitors, or other clinically relevant outcomes from H&E morphology alone or in combination with other modalities.[6,7] Conceptually, this is important because it moves AI beyond object detection into relational pathology, in which the architecture of the tissue itself becomes a predictive signal.

If prospectively validated and standardized across platforms, such approaches could reshape the role of the pathologist from visual estimator of discrete features to curator and interpreter of computationally derived tissue ecosystems. That would represent a deeper paradigm shift than simple case triage. Yet the field has not yet resolved core issues of reproducibility, assay comparability, and causal interpretation. Spatial biomarkers remain one of the most exciting areas in lung pathology AI, but also one of the areas in which methodological discipline is most urgently needed.[1,2,6]

Prognostic modelling and treatment prediction

Another indication that AI is moving beyond a conventional tool paradigm is the increasing ability to derive prognostic and predictive information from routine pathology slides. A computational pathology image signature for early-stage NSCLC reported in EBioMedicine was associated with prognosis and predicted added benefit from adjuvant chemotherapy.[7] Such work illustrates how AI may link tissue morphology to therapeutic value, not merely to diagnosis.

The distinction is fundamental. A diagnostic support tool helps classify what the lesion is. A predictive or prognostic model attempts to estimate what will happen and, in some cases, which intervention will help. Once AI contributes meaningfully at that level, pathology becomes a platform for decision-enabling inference rather than a terminal descriptive endpoint.

Yet this is also where caution is most warranted. Prognostic signatures are particularly vulnerable to hidden confounding, institutional bias, treatment-selection artefacts, and shifts in clinical pathways over time.[1,6,7] The literature therefore supports optimism only if paired with stringent external validation, transparent reporting, and prospective assessment in contemporary treatment contexts. Otherwise, the field risks mistaking retrospective association for clinical utility.

Foundation models and the infrastructural turn

The emergence of pathology foundation models further complicates the tool-versus-paradigm question. Traditional pathology AI often relied on task-specific models trained for narrow outputs. Foundation-model strategies instead pretrain large systems on extensive image corpora and subsequently fine-tune them for particular clinical applications.[2,3] This architecture changes the economics and the epistemology of model development. Instead of building a new model for each narrow task, institutions may increasingly work with reusable representational backbones that support multiple downstream functions.

The 2025 *EGFR* deployment study is a powerful demonstration of this shift, because it used an open-source foundation model as the basis for a clinically meaningful biomarker workflow.[3] Contemporary reviews also describe movement toward high-quality platforms capable of supporting several pathology tasks and toward integrated pipelines that connect radiology, pathology, genomics, and therapeutic stratification.[6] In other words, the field is migrating from isolated algorithms to AI infrastructure.

When AI becomes infrastructural, the paradigm question intensifies. Infrastructure changes what can be routinely known, when it can be known, and who is responsible for interpreting it. In pulmonary pathology, that may ultimately be the strongest argument that AI is not merely another laboratory tool. It is becoming part of the diagnostic substrate itself.

Why the paradigm shift is not yet complete

Despite these advances, the evidence does not yet support triumphalism. The strongest counterargument to paradigm language is that most lung pathology AI remains insufficiently generalized, insufficiently regulated, and insufficiently embedded in routine care.[1,2,5,6] The 2024 external-validation review is especially sobering, because it documents the persistent gap between reported performance and trustworthy deployment.[1] High AUCs derived from restricted cohorts do not settle whether a model is robust across scanners, stains, institutions, specimen types, demographic strata, and shifting case-mix.

This concern is not abstract. Lung pathology is particularly sensitive to small biopsies, cytology-rich material, necrosis, crush artifact,

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variable tumor content, and pre-analytical heterogeneity. Even the successful 2025 *EGFR* deployment study emphasized challenges in low-architecture samples such as cytology and argued for pathologist-in-the-loop strategies and context-sensitive triage.[3] The lesson is not that AI fails, but that it performs within a sociotechnical system rather than outside it.

Interpretability also remains unresolved. Attention maps and saliency methods may be useful for hypothesis generation and error analysis, but they do not, by themselves, guarantee mechanistic transparency or guard against shortcut learning.[2,3,6] Similarly, claims of efficiency must be distinguished from claims of safety. Faster inference is clinically valuable only if the deployment pathway includes governance, monitoring, and clearly defined escalation to human review.

The pathologist-in-the-loop as the most realistic near-term model

The most convincing current model for pulmonary pathology is not replacement of the pathologist but AI-augmented expertise. Recent deployment literature explicitly supports this view, showing that automated outputs are most clinically meaningful when delivered into a workflow in which pathologists retain contextual authority over interpretation, specimen adequacy, discrepancy resolution, and integration with molecular and clinical data.[3] Earlier reviews in lung digital pathology anticipated the same conclusion, arguing that AI would probably assist rather than displace the specialist, particularly in biomarker quantification, triage, and reproducible feature extraction.[2]

This model should not be mistaken for conservatism. Human–AI collaboration may itself represent the true paradigm shift. In such a framework, the pathologist is not reduced to an operator overseeing automation but repositioned as the interpreter of increasingly computational tissue information. The professional role evolves from visual diagnostician alone to expert integrator of morphology, model output, and clinical context (Tables 1 &2).

Table 1 Major AI application domains in pulmonary pathology for lung cancer

Domain	Representative AI objective	Current maturity	Paradigm relevance	Principal limitations
Histological classification and subtyping	Distinguish tumor from non-tumor tissue; classify adenocarcinoma vs squamous carcinoma; assess growth patterns	Relatively mature in retrospective studies and selected external validations[1,2,4]	Moderate — mainly improves consistency and efficiency	Dataset bias, scanner/ stain variability, uncertain operating thresholds, limited prospective validation[1]
Grading and morphometric standardization	Quantify architecture, grade-related patterns, and reproducible morphological signatures	Emerging to moderately mature[2,6]	High — converts visual assessment into computable phenotypes	Need for consensus endpoints, explainability, and robust cross-centre validation[1,2]
Molecular inference from H&E	Predict EGFR and other driver alterations from routine histology	Rapidly advancing; real-world deployment evidence for EGFR triage[3,5]	Very high — may change tissue allocation and diagnostic sequencing	Not a substitute for sequencing; variable performance across specimen types; need for careful triage design[3,5]
Spatial and immune biomarker analysis	Quantify microenvironmental organization, PD-L1–related patterns, and immune architecture	Emerging[2,6]	High — reframes tissue as a spatially computable ecosystem	Reproducibility, assay comparability, uncertain causal interpretation[1,2]
Prognostic and treatment-predictive modelling	Derive risk scores and treatment-benefit signatures from histology	Promising but not fully mature[6,7]	High — links pathology directly to therapeutic decisions	Hidden confounding, temporal dataset shift, need for prospective utility studies[7]
Workflow and triage optimization	Priorities molecular tests, accelerate reporting, preserve tissue, support case review	Increasingly feasible in practice[2,3]	Moderate to high — depends on whether it merely accelerates or reorganizes workflows	Governance, monitoring, integration with LIS, accountability[2,3]

Table 2 AI as tool versus AI as paradigm shift: a critical comparison

Dimension	AI as tool	AI as paradigm shift
Core function	Performs or accelerates predefined tasks such as detection, counting, or subtype suggestion	Changes what can be inferred from a histological slide, including latent molecular, prognostic, and spatial information
Relation to pathology workflow	Sits on top of existing diagnostic processes	Reorganizes triage, tissue stewardship, biomarker strategy, and the role of the pathologist
Unit of analysis	Visible morphological targets	High-dimensional tissue phenotypes, latent representations, multimodal signals

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Table 2 Continued...

Dimension	AI as tool	AI as paradigm shift
Clinical ambition	Improve efficiency, reproducibility, and quality assurance	Alter diagnostic sequencing and expand pathology into predictive, inferential, and integrated decision support
Best current examples in lung cancer	Tumor detection, subtype classification, grading assistance[1,2,4]	EGFR computational biomarker deployment; computational prognostic signatures; reusable foundation-model pipelines[3,6,7]
Current reality in 2026	Already useful and increasingly implementable	Emerging, but incomplete because validation, governance, and standardization remain insufficient[1,2,5,6]

Discussion

The title question—tool or paradigm shift—cannot be answered adequately with a binary choice. In pulmonary pathology, AI is already a robust tool in several specific senses: it can support classification, reduce repetitive burden, standardize selected assessments, and increasingly assist molecular triage.[1–3,5] If that were the whole story, the field could be understood as another chapter in laboratory automation.

It is not the whole story. AI is also changing the conceptual horizon of pathology by suggesting that routine histology encodes a substantially richer layer of biological and therapeutic information than human visual practice has historically extracted.[2–4,6,7] The rise of computational phenotyping, spatial biomarkers, and foundation-model infrastructure supports the view that pulmonary pathology is entering a new phase in which the slide is simultaneously image and data object. This is why the language of paradigm shift is not exaggerated—provided it is used precisely.

Precision matters because premature paradigm language can obscure the unresolved work of validation and governance. The field still needs representative multicentre datasets, standardized reporting, prospective impact studies, demographically fair performance, scanner-robust models, and deployment frameworks that define how model outputs are monitored and contested.[1,2,5,6] The current evidence supports paradigm potential, not paradigm completion.

Three operational priorities emerge for the next phase. First, prospective multicentre validation studies reporting clinical-utility end-points—tissue preservation, turnaround time, discrepancy rates, and impact on treatment decisions—should replace retrospective AUC-centric benchmarking as the primary evidentiary standard. Second, governance frameworks must specify how pathology AI outputs are recorded, audited, and escalated, including mechanisms for monitoring performance drift after deployment. Third, training and credentialing for pathologists and laboratory staff must evolve in parallel, so that expertise in interpreting computational outputs becomes a recognized component of pulmonary pathology practice rather than an informal add-on.

The most defensible conclusion, therefore, is that AI in lung cancer pathology has crossed the boundary of being merely an ancillary computational accessory yet has not fully crossed into a mature replacement paradigm. It is a transitional paradigm in active formation. That framing captures both the intellectual novelty of the field and the discipline required for responsible clinical translation.

Conclusion

Artificial intelligence in lung cancer, viewed through the lens of pulmonary pathology, is no longer adequately described as a simple diagnostic accessory. It has progressed from classification tasks toward computational phenotyping, molecular inference, spatial biomarker discovery, prognostic modelling, and real-world workflow redesign.[1–7] These developments indicate that AI is beginning to transform not only how slides are read, but what slides are understood to contain.

Even so, the strongest current evidence favors a measured conclusion. In 2026, AI in pulmonary pathology represents neither a mature autonomous paradigm nor a mere ancillary instrument. It is better understood as a tool-driven paradigm shift: technically impressive, clinically promising, and already operational in selected settings, yet still dependent on external validation, governance, interoperability, and expert human stewardship. The next decisive stage will not be additional retrospective performance gains alone, but the creation of trustworthy, prospective, pathologist-centered systems that can withstand the variability of real clinical practice.

Contributors

EDC conceptualized the Review, conducted the literature search, drafted the manuscript, and developed the conceptual framework of AI as a transitional paradigm in pulmonary pathology. AH contributed critical revisions, editorial oversight, and refinement of the argument structure. Both authors approved the final version of the manuscript and accept responsibility for the integrity of the work.

Declaration of interests

EDC serves on the editorial board of JCO Clinical Cancer Informatics and co-directs the Pre-graduate Program in Artificial Intelligence and Medicine at Instituto Universitario CEMIC and the Postgraduate at Academia Nacional de Medicina (Buenos Aires, Argentina). AH is Editor-in-Chief of eCurater Publishing. Neither author reports personal fees, grants, stock ownership, or other non-financial relationships with the developers of the AI systems or the diagnostic platforms cited in this Review. No industry funding was received for this work.

Declaration of use of artificial intelligence

In line with emerging editorial guidance from the International Committee of Medical Journal Editors (ICMJE) and The Lancet group of journals on the transparent use of generative artificial intelligence in scientific writing, the authors declare that large language model (LLM) assistance (Anthropic's Claude) was used during the preparation of this Review to support structural revision, consistency checking, and copy-editing of the manuscript. No AI system was used to generate primary data, to perform autonomous literature searches, to fabricate citations, or to formulate scientific claims. All interpretations, arguments, conclusions, and bibliographic verifications were made by the named human authors, who take full responsibility for the integrity and content of this article.

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Data sharing

No primary data were generated for this Review. All cited sources are publicly available through their respective publishers.

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Conflicts of interest

We declare that there is no conflict of interest of any kind.

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