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# Automation and Artificial Intelligence in Clinical Pathology: Transforming Diagnostic Accuracy

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## Abstract

The accelerating integration of automation and artificial intelligence (AI) into clinical pathology underscores the urgent need for a comprehensive review of their transformative impact. While traditional diagnostic methods have long served as the backbone of pathology, emerging digital tools are redefining accuracy, efficiency, and scalability in unprecedented ways. However, despite rapid technological strides, there remains a knowledge gap regarding practical implementation, validation, and standardization of AI-assisted diagnostics. Therefore, this review consolidates current advancements, evaluates practical applications, and highlights the remaining challenges that demand collective attention. This review discusses the evolution of digital pathology and its synergy with AI technologies in improving diagnostic workflows. It examines how AI-driven algorithms support tissue image segmentation, tumor classification, and biomarker quantification with enhanced precision. Applications in subspecialties such as nephropathology, gastrointestinal pathology, and neuroimaging are analyzed to illustrate the breadth of AI's utility. The role of automation and robotics in laboratory settings is explored, emphasizing improvements in high-throughput testing, error reduction, and remote diagnostics. Case studies including PathChat, TriPath, and Whole-Slide Image (WSI) based systems demonstrate real-world validation of AI's diagnostic and prognostic capabilities. The review also critically addresses the limitations of current AI tools, such as algorithmic bias, data integrity, and challenges in clinical workflow integration. Furthermore, ethical, regulatory, and infrastructural considerations are discussed to provide a balanced perspective on the readiness of AI for routine clinical practice. Looking ahead, the review outlines how integration with multi-omics data and explainable AI frameworks could propel the field towards truly personalized medicine. It emphasizes the need for interdisciplinary collaboration, large-scale validation, and robust regulatory guidelines to ensure safe and equitable adoption. By addressing these prospects and challenges, the review aims to guide future innovations that will cement AI and automation as indispensable allies to human expertise in clinical pathology.

**Keywords:** Artificial intelligence, Automation, Clinical pathology, Digital pathology, Diagnostics, Machine learning, Medical imaging, Workflow optimization

## Introduction

The integration of automation and AI into clinical pathology is revolutionizing diagnostic accuracy across various medical disciplines (Table 1) [1-3]. Recent literature underscores the transformative potential of these technologies in enhancing diagnostic workflows, improving precision, and facilitating early detection of diseases [4-6]. Digital pathology has emerged as a pivotal advancement, enabling large-scale data storage, retrieval, and analysis that support the development of robust diagnostic algorithms [7]. The transition from traditional glass slides to digital images has opened avenues for applying AI-driven image analysis techniques, which assist pathologists in tissue examination, segmentation, and quantification of histological structures [8]. Such developments are particularly evident in kidney pathology, where AI algorithms have been employed to identify histological features and predict clinical outcomes, demonstrating significant progress in disease classification and prognosis [8].

In neuro- and gastrointestinal pathology, AI's role extends to neuroimaging and endoscopic image analysis [9-11]. For instance, AI applications in gastrointestinal endoscopy focus on analyzing endoscopic images to improve lesion detection and characterization, with expert reviews highlighting the importance of AI in enhancing diagnostic accuracy in gastrointestinal diseases [12]. Similarly, AI-based processing algorithms for computed tomography images have been proposed to interpret pathological changes, such as in COVID-19 diagnosis, by highlighting objects of interest and contrasting features based on color coding and image dynamics [13]. The broader impact of AI in diagnostics is also evident in laboratory settings, where AI systems are integrated into preanalytical, analytical, and postanalytical phases to optimize workflow and accuracy [2]. Automated systems, such as high-throughput analyzers and microfluidic devices, have improved the reproducibility and efficiency of platelet function testing, exemplifying how automation enhances diagnostic consistency and throughput [14].

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**Table 1:** Applications of AI and automation in subspecialties of clinical pathology.

| Subspecialty | AI application | Key benefits | Notable studies/Tools |
|---|---|---|---|
| Nephropathology | Histological image analysis, outcome prediction | Improved disease classification and prognosis | AI algorithms for glomerular pathology |
| Gastrointestinal pathology | Endoscopic image analysis | Enhanced lesion detection and classification | AI in colorectal polyp detection |
| Neuropathology | Neuroimaging analysis | Accurate identification of pathological changes | AI in neuroimaging for early diagnosis |
| Hematopathology | Automated slide scanning and classification | Faster lymphoma subtyping and risk stratification | Convolutional neural networks for lymphoma |
| Oncology (general) | Tumor subtyping, biomarker quantification | Improved precision in targeted therapy decisions | WIFPS |
| Laboratory diagnostics | Preanalytical and postanalytical workflow | Increased efficiency, reduced human error | High-throughput analyzers, microfluidics |
| Breast pathology | Histopathology image classification | Higher sensitivity for carcinoma detection | Ensemble VGG16/VGG19 models |
| Prostate pathology | WSIs and normalization for cancer detection | Consistent results across scanning systems | Cycle-GAN normalization with U-Net |

Despite these advancements, challenges remain in the widespread adoption of AI and automation. For example, the reliability of AI tools like ChatGPT in complex clinical scenarios has been questioned, with studies indicating limitations in handling intricate pathologies and in identifying incorrect presentations [15]. Additionally, the implementation of digital and AI technologies requires overcoming clinical, technical, and ethical hurdles to fully realize their potential in routine practice [7]. In summary, current literature demonstrates that automation and AI are significantly transforming clinical pathology by improving diagnostic precision, enabling large-scale data analysis, and streamlining workflows. These innovations are paving the way for more accurate, efficient, and personalized diagnostic approaches, although ongoing efforts are needed to address existing limitations and facilitate broader clinical integration [16-18].

The integration of automation and AI in clinical pathology is revolutionizing the landscape of diagnostic accuracy. As the field evolves, AI technologies are increasingly being employed to enhance the precision, efficiency, and reproducibility of diagnostic processes [19-21]. This article explores the transformative impact of AI in clinical pathology, highlighting its applications, benefits, and the challenges that lie ahead.

## Advancements in AI Applications

AI has shown remarkable potential in various subspecialties of pathology, particularly in digital pathology, where it aids in the analysis of digitized images [22-24]. Recent studies have demonstrated that AI can significantly improve diagnostic performance across multiple applications. For instance, a systematic review by Kunze et al. [25] revealed that AI models for detecting anterior cruciate ligament and meniscus tears achieved an area under the curve (AUC) ranging from 0.895 to 0.980, indicating high diagnostic accuracy. Similarly, Steiner et al. [26] emphasized the promise of AI in digital pathology, noting its ability to enhance diagnostic accuracy and efficiency while addressing the existing translation gap into clinical practice. In gastrointestinal endoscopy, AI applications have transformed image analysis, enabling the detection and classification of various conditions, including colorectal polyps and early gastric cancer [12]. The implementation of deep learning techniques has shown potential to improve diagnostic accuracy and reduce the workload of healthcare professionals [27]. Furthermore, the integration of AI in nephropathology has led to advancements in histological analysis, improving precision and prognostic capabilities [8].

### AI in pathology diagnostics

- AI technologies, including deep learning and machine learning, are being utilized to automate the analysis of pathological images, reducing the need for manual evaluation and increasing diagnostic accuracy [1, 28].
- AI-driven tools are particularly effective in detecting subtle patterns in complex cases, such as cancer, which might be missed through manual examination [7].
- The integration of AI with digital pathology allows for the precise characterization of tumors, aiding in targeted therapy decisions and personalized medicine [7].

### Automation and robotics in laboratories

- Automation and robotics have streamlined laboratory processes, reduced errors and increasing efficiency in sample processing and data analysis [29].
- These technologies facilitate high-throughput environments and remote diagnostics, enhancing the accessibility and precision of laboratory practices [29].
- Automated whole slide imaging scanners provide high-resolution images that are crucial for integrating imaging into all aspects of pathology reporting [1].

### Digital pathology and AI synergy

- Digital pathology, combined with AI, enables the automation of repetitive processes such as tissue segmentation and biomarker quantification, decreasing inter-observer variability [7].
- The digitalization of pathology laboratories enhances workflow efficiency and allows for large-scale data storage and retrieval, paving the way for robust diagnostic algorithms [7].

- AI applications in nephropathology, for instance, have shown potential in improving diagnostic accuracy and efficiency by identifying histological structures and predicting clinical outcomes [30].

## Enhancing Diagnostic Accuracy

The integration of AI into clinical pathology has significantly enhanced diagnostic accuracy by leveraging advanced algorithms to analyze complex datasets [31-33]. AI's ability to identify subtle patterns in pathological images, such as those found in cancer tissues, has reduced the likelihood of human error and improved the precision of diagnoses [34-36]. For example, deep learning models have been successfully applied to breast cancer pathology, enabling more accurate tumor classification and grading while providing valuable prognostic insights. These advancements allow pathologists to focus on interpreting results and making critical clinical decisions, thereby optimizing workflow efficiency [37].

AI-driven tools have also demonstrated remarkable success in reducing inter-observer variability, a longstanding challenge in traditional pathology practices [38, 39]. By standardizing the analysis of histological samples, AI ensures consistent and reliable diagnoses, particularly in high-stakes scenarios like cancer detection [40-42]. Studies have shown that AI algorithms can achieve diagnostic performance comparable to, or even surpassing, that of experienced pathologists in specific tasks. This consistency is crucial for improving patient outcomes and fostering trust in AI-assisted diagnostics [43]. Moreover, AI-driven algorithms have been shown to reduce inter-observer variability, a common challenge in traditional pathology practices. This reduction in variability is crucial for ensuring consistent and reliable diagnoses, particularly in high-stakes environments such as cancer diagnosis [7].

The synergy between AI and digital pathology has further amplified diagnostic capabilities [44-46]. Digital platforms enable the storage and retrieval of vast amounts of pathological data, which AI algorithms can analyze rapidly and accurately [47-49]. For instance, in nephropathology, AI has been used to identify histological structures and predict clinical outcomes, enhancing both diagnostic accuracy and prognostic capabilities. This combination of digital infrastructure and AI analysis paves the way for more efficient and scalable diagnostic processes [50]. Despite these advancements, the role of human expertise remains indispensable. AI systems excel at processing large volumes of data and identifying patterns, but they lack the contextual understanding and clinical judgment of trained pathologists. Collaborative approaches, where AI assists in preliminary analyses and flagging potential issues, allow pathologists to focus on complex cases and integrate AI findings with their own expertise [51-53]. This partnership ensures a balanced and comprehensive diagnostic process.

The potential of AI to enhance diagnostic accuracy extends beyond histopathology. In fields like neuroimaging and gastrointestinal endoscopy, AI applications have improved lesion detection and characterization, leading to earlier and more accurate diagnoses [54, 55]. For example, AI-powered endoscopic systems can highlight suspicious areas in real-time, aiding clinicians in identifying precancerous lesions or early-stage tumors [56, 57]. These innovations underscore the transformative impact of AI across diverse medical disciplines. Looking ahead, the continued refinement of AI algorithms and their integration with emerging technologies, such as genomics and molecular profiling, holds promise for further advancements in diagnostic accuracy [58-60]. However, ongoing efforts are needed to address challenges like algorithmic bias, data quality, and the need for robust validation frameworks. By fostering collaboration between AI developers, clinicians, and regulatory bodies, the field can ensure that these technologies are deployed responsibly and effectively, ultimately benefiting patient care [61, 62].

## Case Studies

The integration of digital pathology with AI technologies is revolutionizing traditional diagnostic practices, enabling more precise and reliable disease detection and prognosis. This transformation is driven by advancements in digital imaging, machine learning, and computational tools, which collectively improve the quality and speed of pathology workflows.

PathChat [63], a multimodal generative AI copilot for human pathology, demonstrated state-of-the-art performance and showed significant capabilities across various applications in pathology (Figure 1). The key results highlight its superiority over existing models in diagnostic accuracy and its potential as an interactive vision-language AI copilot. PathChat convincingly outperformed open-source baselines like LLaVA 1.5 and LLaVA-Med in diagnostic accuracy for multiple-choice questions. In the image-only evaluation setting, PathChat achieved an accuracy of 78.1%, which was significantly higher than LLaVA 1.5 (+52.4%) and LLaVA-Med (+63.8%). When clinical context was provided alongside the image, PathChat's accuracy improved to 89.5%, outperforming LLaVA 1.5 (+39.0%) and LLaVA-Med (+60.9%). This indicates that PathChat effectively leverages multimodal information for more accurate diagnoses. PathChat also consistently outperformed GPT-4V, a commercial multimodal AI assistant, in both image-only and image-with-clinical-context settings. For instance, with clinical context, PathChat achieved 90.5% accuracy compared to GPT-4V's 63.5% (+26.9%). PathChat produced more accurate and pathologist-preferable responses to diverse open-ended queries related to pathology compared to other MLLMs. In a human expert evaluation where seven pathologists ranked model responses, PathChat had a favorable median win rate of 56.5% against GPT-4V, 67.7% against LLaVA 1.5, and 74.2% against LLaVA-Med. For a subset of open-ended questions where pathologists reached a consensus on correctness, PathChat scored an overall accuracy of 78.7%, a 26.4% improvement over GPT-4V's 52.3%. It also showed substantial improvements over LLaVA 1.5 (+48.9%) and LLaVA-Med (+48.1%). PathChat's responses were particularly superior to GPT-4V in categories requiring examination of histology images, such as microscopy and diagnosis, with accuracies of 73.3% and 78.5% respectively, compared to GPT-4V's 22.8% and 31.6%. While GPT-4V showed higher scores in clinical and ancillary testing categories (88.5% and 89.5% respectively), PathChat's performance in these areas was also respectable at 80.3%. However, the statistical significance of GPT-4V's lead in these categories was not conclusive. PathChat can analyze and describe notable morphological details in histology images and answer questions requiring background knowledge in pathology and general biomedicine. It can combine visual features with clinical context and medical knowledge, enabling a wide range of applications. PathChat supports interactive multi-turn conversations, allowing it to serve as a consultant for human-in-the-loop differential diagnosis, which is particularly valuable for complex workups or in resource-limited settings. In summary, PathChat represents a significant advancement in computational pathology, offering a robust and accurate AI copilot that can assist

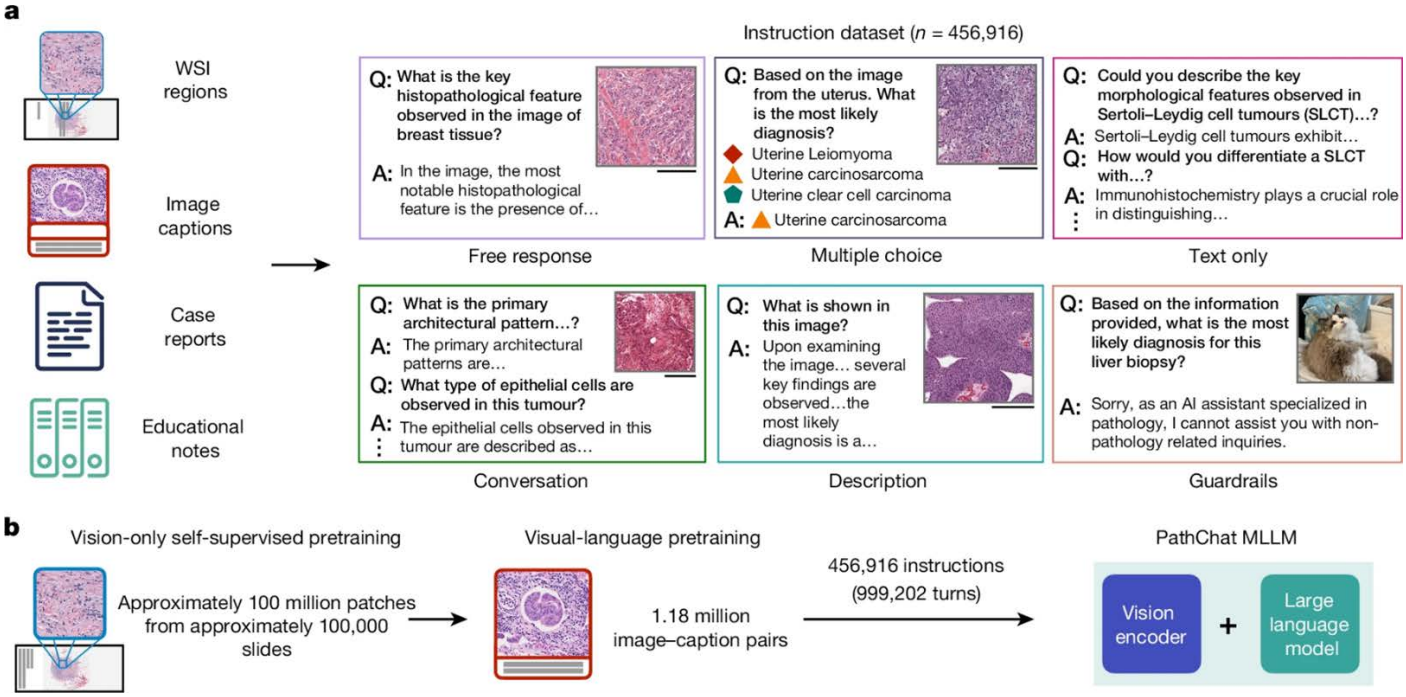


**Figure 1:** Curation of instruction-following dataset and PathChat overview [63].

human pathologists in various diagnostic, educational, and research tasks by effectively integrating visual and natural language information.

A study by Song et al. [64] introduces TriPath, a deep-learning platform designed for analyzing 3D pathology samples and predicting clinical outcomes (Figure 2). The results highlight the superior performance of 3D volume-based prognostication compared to traditional 2D slice-based methods and pathologist baselines. This approach effectively addresses challenges related to sampling bias and tissue heterogeneity inherent in 2D histopathology. TriPath, utilizing 3D tissue volume, consistently outperforms 2D slice-based methods for patient prognostication. This is attributed to its ability to capture comprehensive 3D morphologies, which are often missed by limited 2D cross-sections. The 3D prognostication achieved by TriPath surpasses the performance of pathologist baselines, indicating its strong clinical potential. For instance, on the OTLS cohort, the whole-volume 3D approach (AUC, 0.860) showed a statistically significant difference compared to 2D planes (AUC, 0.816). Similarly, for the microCT cohort, whole-volume 3D (AUC, 0.749) outperformed 2D planes (AUC, 0.634) and clinical baselines. Larger tissue volumes, as analyzed by TriPath, effectively mitigate sampling bias, which is a significant limitation of traditional 2D histopathology where limited cross-sections may not fully represent the tissue. The study found that using the entire volume (whole-volume 2D) provided better performance than using only a portion (single plane), and 3D features further improved this. The platform accounts for tissue heterogeneity by comprehensively capturing 3D morphological features, leading to more accurate risk prediction. Ablation analysis showed that incorporating larger portions of the tissue volume led to an upward trend in AUC, confirming the benefits of greater tissue volume. TriPath uses an attention-based aggregation module and integrated gradient analysis to identify important instances and regions contributing to prognostic decisions, providing interpretability without requiring additional pathologist annotations. High IG scores were associated with regions indicating unfavorable prognosis (e.g., infiltrative carcinoma resembling Gleason pattern 4), while low IG scores correlated with favorable prognosis (e.g., benign glands). This demonstrates that TriPath learns to assign prognostic attribution across the cohort based on the extent of prognostic morphologies. In summary, the paper demonstrates that TriPath's 3D volume-based analysis significantly improves patient prognostication in prostate cancer by overcoming the limitations of 2D methods, providing superior performance, and offering valuable insights into morphological features linked to disease progression.

A study by Chen et al. [65] developed and validated a WSI-based Immunohistochemical Feature Prediction System (WIFPS) designed to improve the subtyping of lung cancer (Figure 3). The key results demonstrate the system's proficiency in predicting immunohistochemistry (IHC) phenotypes and its potential in detecting gene mutations directly from WSIs. The WIFPS effectively predicted the IHC status of nine subtype-specific biomarkers: CK7, TTF-1, Napsin A, CK5/6, P63, P40, CD56, Synaptophysin, and Chromogranin A. The system achieved impressive average AUCs of 0.912, 0.906, and 0.888 across different validation datasets (total, external surgical resection, and biopsy specimens, respectively). Overall diagnostic accuracies were high: 0.925 for total validation datasets, 0.941 for external surgical resection specimens, and 0.887 for biopsy specimens. The WIFPS's histological subtyping performance was comparable to that of general pathologists. Cohen's kappa values, which measure agreement, ranged from 0.7646 to 0.8282, indicating good consistency. The diagnostic accuracy for subtyping reached 0.903 in the entire validation set, 0.948 in surgical resection specimens, and 0.889 in biopsy specimens, with sensitivities greater than 0.813 and specificities greater than 0.912. The WIFPS demonstrated the ability to predict the IHC status of anaplastic lymphoma kinase, programmed death-1, and programmed death-ligand 1. ROC curve analysis showed AUCs of 0.917 for anaplastic lymphoma kinase, 0.576 for programmed death-1, and 0.525 for programmed death-ligand 1. The authors note that the limited number of cases for these markers suggests a need for further optimization with larger datasets. The system could also predict epidermal growth factor receptor (EGFR) and KRAS mutation status. AUCs for EGFR and KRAS mutation status ranged from 0.525 to

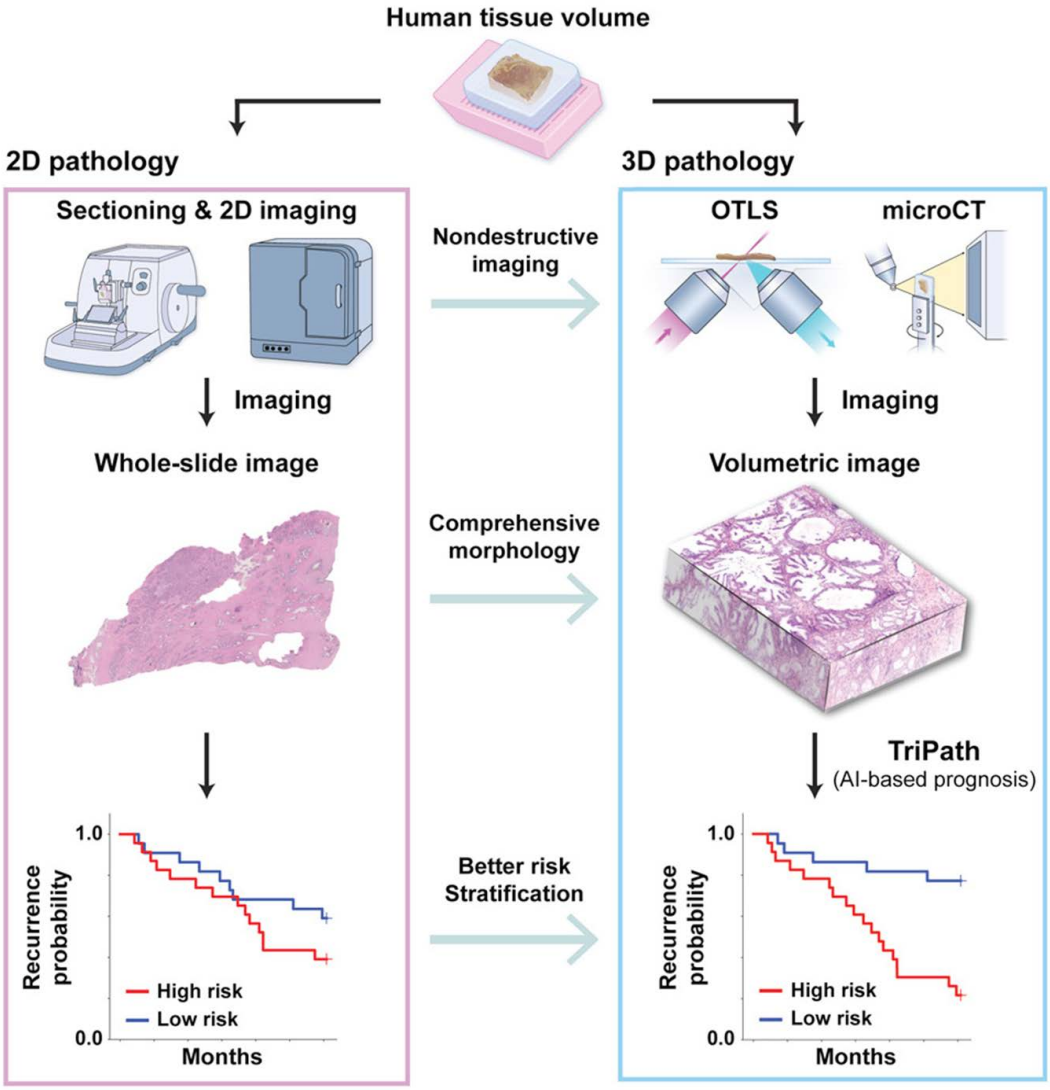


**Figure 2:** Analysis of 3D pathology samples using weakly supervised AI [64].

0.917. The predictive performance was modest (AUC: 0.683 for EGFR; 0.545 for KRAS) in the independent validation set, indicating that more data could improve the model's performance. WIFPS showed high agreement rates with expert pathologists in IHC interpretation, with Cohen's kappa values ranging from 0.7903 to 0.8891 for individual biomarkers. The system's performance in histological subtyping was similar to that of general pathologists. The WIFPS can help address challenges in clinical diagnosis, such as insufficient tissue amounts or the unaffordability of additional tests, by providing an alternative approach to improve lung cancer subtyping without these limitations. In summary, the WIFPS is a promising deep learning system that can accurately predict various IHC markers and gene mutations directly from H&E-stained WSIs, offering a valuable tool to assist pathologists in lung cancer diagnosis and subtyping, especially in cases with limited tissue or resources.

A study by Hameed et al. [66] presents the results of an ensemble deep learning approach for classifying breast cancer histopathology images, focusing on the performance of individual VGG16 and VGG19 models, and their ensemble. The primary objective was to accurately classify carcinoma images. Fully trained VGG16 model showed an average recall (sensitivity) of 94.55% (±2.59) for the carcinoma class. The overall accuracy was 91.41% (±3.40), with an average F1 score of 91.38% (±3.42). Fine-tuned VGG16 achieved an average recall of 94.09% (±3.35) for the carcinoma class. Its average overall accuracy was 91.67% (±3.69), and the average F1 score was 91.63% (±3.69). Fully trained VGG19 model demonstrated an average recall (sensitivity) of 95.45% (±3.41) for carcinoma images, which is 0.9 percentage points higher than the fully trained VGG16 model. The overall accuracy was 90.35% (±1.35), with an average F1 score of 90.31% (±1.35). Fine-tuned VGG19 approach yielded an average recall of 95.68% (±3.15) for carcinoma cases, reflecting a 1.59%-point improvement over the fine-tuned VGG16 model. Its average overall accuracy was 91.67% (±2.99), and the average F1 score was 91.63% (±3.03). The study employed an ensemble strategy by averaging the predicted probabilities from fine-tuned VGG16 and fine-tuned VGG19 models. This method aims to leverage the strengths of both models for more robust classification. The ensemble of fine-tuned VGG16 and fine-tuned VGG19 models achieved a sensitivity of 97.73% for the carcinoma class and an overall accuracy of 95.29%. It also yielded an F1 score of 95.29%. The recall value for the carcinoma class was consistently 97.73% in both fully

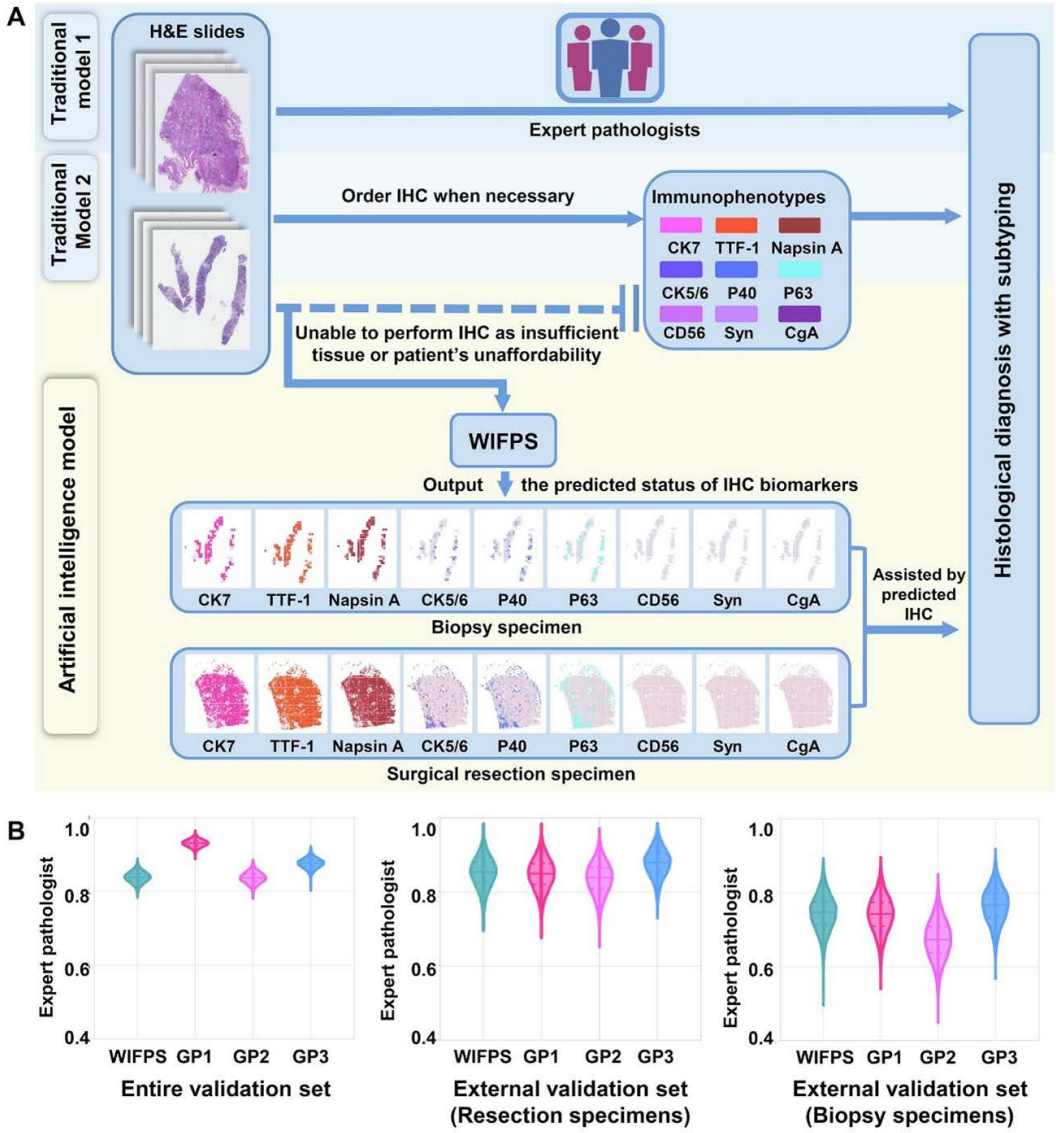


**Figure 3:** Clinical application scenario of the WIFPS and its comparison with general and expert pathologists for histologic subtyping [65].

trained and fine-tuned ensemble approaches. However, the fine-tuned ensemble approach offered higher overall accuracy and F1 score compared to the fully trained ensemble. The proposed deep learning approach, particularly the ensemble model, demonstrated competitive classification performance for complex histopathology images of breast cancer, especially for carcinoma images. Despite using a comparatively smaller dataset, the results were competitive with other novel deep learning frameworks that often utilize larger datasets. For instance, previous studies using the BreakHis dataset reported accuracies ranging from 84.0% to 96.7% for 200x magnification, showcasing the effectiveness of the proposed ensemble method. In summary, the ensemble of fine-tuned VGG16 and VGG19 models proved to be highly effective for breast cancer histopathology image classification, particularly for identifying carcinoma, offering superior performance compared to individual models and competitive results against existing state-of-the-art methods, despite the use of a smaller dataset.

A study by El Achi et al. [67] evaluated the performance of a deep learning model, specifically a convolutional neural network algorithm, for the automated diagnosis of lymphoma across four categories: benign lymph node, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), and small lymphocytic lymphoma (SLL). The results demonstrated high diagnostic accuracy, especially when considering multiple images per case. The convolutional neural network model achieved an overall diagnostic accuracy of 95% when predicting the diagnosis based on single, random images. Out of 240 test images, 228 were correctly diagnosed, while 12 images received an incorrect diagnosis. Specifically, among the 12 misdiagnosed images, 4 SLL images were incorrectly predicted as benign, 4 other SLL images were predicted as DLBCL, and 4 benign images were predicted as BL. When incorporating all five representative images for each case and applying a majority voting strategy (where at least three out of five images had to agree), the model achieved 100% accuracy. All 48 sets of images were correctly diagnosed using this method. This finding suggests that relying on a single image for diagnosis is too stringent, and a more robust microscopic diagnosis requires considering all representative images to exclude outliers. The optimized convolutional neural network used specific hyper-parameters for its layers: a first convolutional layer with a 5x5

kernel and 20 feature maps (tanh activation), a first pooling layer with a 3x3 kernel and 3x3 stride (max-pooling), a second convolutional layer with a 5x5 kernel and 50 feature maps (tanh activation), a second pooling layer with a 3x3 kernel and 3x3 stride (max-pooling), a first fully connected layer with 500 hidden nodes (tanh activation), and a second fully connected output layer with 4 nodes (softmax activation). In summary, this preliminary study provides proof of concept for integrating automated lymphoma diagnostic screening into future pathology workflows. The high accuracy, particularly with set-by-set analysis, highlights the potential of deep learning to augment pathologists' productivity by providing reliable diagnostic assistance for common lymphoma types.

A study by Yu et al. [68] investigated the use of machine learning, specifically deep neural networks and XGBoost, to classify primary intestinal T-cell lymphomas (PITLs) into monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL) and intestinal T-cell lymphoma, not otherwise specified (ITCL-NOS). The key results demonstrate the effectiveness of this approach in segmenting nuclei, quantifying morphological features, and accurately classifying these challenging lymphoma subtypes. The deep neural network developed for detecting and segmenting lymphocyte nuclei achieved strong performance. It had an average precision of 0.943 on the validation set and 0.881 on the testing set for segmenting lymphoma nuclei. For the testing set, the model demonstrated a precision (positive predictive value) of 0.911 and a recall (sensitivity) of 0.868. The model successfully detected a large number of nuclei, with an average of 892.18 ± 254.80 nuclei per high-power field (HPF). This enabled the computation of quantitative nuclear morphometrics, which are crucial for analysis. The XGBoost model, utilizing only morphological feature measurements, achieved an AUC of 0.966 (95% CI: 0.949 to 0.984) for classifying MEITL versus ITCL-NOS. This performance was significantly superior to a deep convolutional neural network directly trained on images, which achieved an AUC of 0.820 (0.734 to 0.906). Adding IHC phenotypes (CD8 and CD56 expression) as inputs to the XGBoost model did not significantly improve its discriminative power, yielding an AUC of 0.955 (95% CI: 0.935 to 0.975) (p value = 0.412). This indicates that morphological features alone are highly effective for classification. The most important morphological features for classification by the XGBoost model were the variance in perimeter, the variance in nuclear area, and the mean of nuclear irregularity. When IHC phenotypes were included, CD56 and CD8 expression ranked highly, second only to the variance in perimeter. Statistical analysis using a General Linear Model revealed statistically significant differences in several morphological feature measurements between MEITL and ITCL-NOS. For instance, five out of seven measurements in variance and mean showed significant differences between the two disease subtypes. Features related to cell size, such as perimeter and area, had a stronger effect on variance than on the mean ($p < 0.001$). The two disease subtypes could be visually separated by plotting the variance in nuclear perimeter against the variance in nuclear irregularity. MEITL cases typically showed smaller variance in both, with a linear correlation, while ITCL-NOS cases exhibited higher variance. The model demonstrated a 1:1 ratio prediction for the four borderline cases, which were difficult to distinguish morphologically. Two cases were predicted as MEITL, and two as ITCL-NOS, highlighting the model's ability to aid in challenging diagnoses. In summary, the study successfully demonstrated an accurate and human-interpretable machine learning approach for classifying PITLs, highlighting the critical role of quantitative nuclear morphometrics and the superior performance of XGBoost over direct convolutional neural network application for this task.

A study Zhang et al. [69] presents the results of developing and validating deep learning models for rhabdomyosarcoma (RMS) subtype classification and embryonal RMS (eRMS) prognosis prediction using pathology images. The trained RMS subtype classification model, tested on 1674 image patches, achieved an overall patch-level prediction accuracy of 87.9% for five classes (aRMS, eRMS, scRMS, other tissues, and white background). Specifically, for cancerous tissue, the accuracy was 84.0% for aRMS, 90.2% for eRMS, and 76.3% for scRMS. The model also showed high accuracy for noncancerous tissues (87.5%) and white background (99.7%). When aggregating patch-level predictions to the whole slide level, the model correctly classified 29 out of 31 aRMS slides and 144 out of 161 eRMS slides. The AUC values for slide-level predictions were 0.94 for aRMS and 0.92 for eRMS, indicating strong performance in distinguishing these subtypes. The eRMS prognostic model, developed using transfer learning, successfully stratified patients into high- and low-risk groups. This model was trained using 3074 image patches from low- or high-risk patient slides. In the test data set of 136 eRMS patients, the model separated them into 42 low-risk and 94 high-risk predictions. Patients in the predicted low-risk group showed significantly better survival, with a much lower chance of relapse/progression, second malignancy, or death, compared to the high-risk group (likelihood ratio test; $p = 0.02$). The Cox proportional hazards model predicted a hazard ratio of 4.55 (95% CI: 1.04 to 19.96; $p = 0.04$) for the high- versus low-risk group. After adjusting for patient age and sex, the image-based prognostic model remained a significant independent prognostic factor, with a hazard ratio of 4.64 (95% CI: 1.05 to 20.57; $p = 0.04$). In summary, this study demonstrates the successful application of deep learning algorithms to classify RMS subtypes and predict prognosis from histopathology images. The models show high accuracy and significant prognostic value, suggesting their potential as aids in pathology evaluation and risk stratification for RMS patients, particularly in the context of eRMS.

A study by Swiderska-Chadaj et al. [70] investigated the impact of scanning systems and normalization techniques on the performance of convolutional neural networks for automatic prostate cancer detection in WSIs. In the initial three-fold cross-validation experiment, U-Net, DenseNetFCN, and EfficientNet models were compared for their performance on the development set. U-Net demonstrated superior performance with an AUC of 0.98 ± 0.005, outperforming DenseNetFCN (0.97 ± 0.008) and EfficientNet (0.97 ± 0.009). At the patch level, U-Net achieved a Dice coefficient of 0.80 (Jaccard index: 0.67), while DenseNetFCN achieved 0.74 (Jaccard index: 0.59). The analysis at the whole-slide level for the full development set showed U-Net performing best in terms of AUC. For the two independent test sets (IT1 and IT2), the U-Net model, trained on the full development set, achieved AUCs of 0.92 and 0.83, respectively. The performance drop on IT2 (approximately 15%) was noted as unacceptable for clinical adoption, while IT1's drop (around 6%) was considered reasonable. The study found that performance deterioration on independent test sets could be partly attributed to scanner variability. Re-scanning IT2 slides on the same Philips scanner used for the development set improved the AUC from 0.83 to 0.88, reducing the performance drop from 15% to 10%. For IT1, re-scanning had a slightly negative impact on AUC (0.92 to 0.91) but improved accuracy (0.83 to 0.87). Applying color normalization (WSICS algorithm) as a pre-processing step resulted in a 0.04 AUC improvement for IT1 and a 0.02 AUC deterioration for IT2. Cycle-GAN-based style normalization showed a significant improvement in AUC, ranging from 0.06 to 0.14 for both test sets. This method notably reduced false positive detections and increased specificity at a sensitivity of 1.0. After Cycle-GAN normalization, the AUC for the independent sets (0.97 and 0.98) aligned closely with the cross-validation results on the development

set (0.98), indicating that normalization can help close the generalization gap. The proposed method demonstrated relative robustness to scanner differences. The results highlight the potential of deep learning systems as a triage tool, especially at high sensitivity (e.g., >0.99), to reduce the workload of pathologists by automatically pre-screening prostate biopsies. In summary, the study demonstrates that while deep learning models show strong potential for prostate cancer detection, factors like scanner variability significantly impact performance. Normalization techniques, particularly Cycle-GAN based style normalization, are crucial for improving model robustness and generalization across different scanning and staining conditions, helping to bridge the gap between development and real-world application performance.

A study by Tabibu et al. [71] demonstrates the application of deep learning frameworks for the automatic classification of Renal Cell Carcinoma (RCC) subtypes and the prediction of patient survival outcomes using digital histopathological images. The key results highlight the efficacy of convolutional neural networks and a novel support vector machine-based approach in achieving these goals. Convolutional neural networks trained on WSIs effectively distinguished clear cell (KIRC) and chromophobe (KICH) RCC from normal tissue. The patch-wise classification accuracy on the test set was 93.39% for KIRC and 87.34% for KICH at 40x resolution. A slide-wise analysis, which involved counting the percentage of positively classified patches in a slide, yielded an AUC of 0.98 for KIRC and 0.95 for KICH using Resnet 34. This indicates strong performance in identifying cancerous regions. The study found that better performance was generally obtained for KIRC when trained on 40x images and for KICH when trained on 20x images, suggesting complex morphological distinguishing features between cancers. A convolutional neural network trained to distinguish clear cell (KIRC), chromophobe (KICH), and papillary (KIRP) RCC achieved a patch-wise classification accuracy of 87.69% and a micro-average AUC of 0.91 with a Kappa score of 0.794. However, initial recall scores were around 83%, indicating some misclassification, particularly for KIRP (70%) due to data imbalance. To address data imbalance, a novel directed acyclic graph support vector machine method was introduced. This approach converts the multi-class classification problem into multiple binary classification tasks. When combined with the convolutional neural networks, the directed acyclic graph support vector machine significantly improved patch-wise accuracy by 5% and increased the micro-average AUC by 0.03. The classification score for KIRP also increased by 10%. Two additional strategies were applied to overcome class imbalance: (i) data augmentation: Balancing the class distribution through data augmentation of the minority class resulted in an accuracy of 91.47% with a Kappa score of 0.859, and (ii) weighted resampling: Training the convolutional neural network with weighted resampling, giving more weight to the minority class, achieved an accuracy of 92.16% with a Kappa score of 0.871. Both methods significantly improved subtype classification accuracy and applying directed acyclic graph support vector machine further enhanced performance. The study successfully extracted morphological features from high-probability tumor regions identified by the convolutional neural network to predict patient survival outcomes for KIRC. The generated risk index, based on both tumor shape and nuclei features, was significantly associated with patient survival. Thirteen tumor shape features and six nuclei shape features were found to be significantly associated with patient survival ($p < 0.05$). Total area ($p = 1.5e-6$, HR = 2.398) and total perimeter ($p = 1.49e-5$, HR = 2.485). Total convex area ($p = 2.2e-7$, HR = 2.576) and total major axis ($p = 0.000614$, HR = 2.252). An integrative model combining image features showed a significant association with survival outcome ($p = 3.68e-6$). Multivariate analysis further indicated that predicted risk indices and stages of tumor significantly impact survival. In summary, the paper demonstrates that deep learning can play a crucial role in both cancer diagnosis and prognosis by accurately classifying RCC subtypes and predicting patient survival based on histopathological images. The integration of convolutional neural networks with directed acyclic graph support vector machine effectively addresses data imbalance, and the extracted morphological features provide valuable prognostic information.

While AI and automation are transforming clinical pathology, it is important to consider the broader implications of these technologies. The shift towards digital and AI-driven pathology requires careful consideration of ethical, regulatory, and infrastructural challenges to ensure responsible implementation. As the field continues to evolve, balancing technological advancements with these considerations will be crucial for maximizing the benefits of AI in clinical pathology.

## Challenges and Future Directions

Despite the significant progress in AI-driven clinical pathology, several challenges hinder its widespread adoption (Table 2). One major concern is data integrity, as AI models rely on high-quality, diverse datasets for training [72, 73]. Biases in these datasets, whether due to underrepresentation of certain populations or inconsistent sample collection- can lead to algorithmic biases, resulting in skewed or inaccurate diagnoses. Ensuring robust data governance and inclusive datasets is critical to developing reliable AI tools that perform equitably across diverse patient groups [74].

Another challenge lies in the integration of AI into existing clinical workflows [75, 76]. Many pathology laboratories still operate with traditional methods, and transitioning to AI-assisted diagnostics requires substantial infrastructural and procedural changes [77]. Clinicians and technicians must be trained to use these new tools effectively, and workflows must be redesigned to accommodate AI without disrupting efficiency [78, 79]. Resistance to change and the steep learning curve associated with AI adoption further complicate this transition, necessitating comprehensive training programs and stakeholder engagement [80, 81]. The phenomenon of automation bias, where clinicians may overly rely on

**Table 2:** Challenges and future directions in AI integration.

| Challenge | Description | Suggested approach |
|---|---|---|
| Data bias and quality | Underrepresentation and inconsistency in training datasets | Develop diverse, high-quality datasets |
| Workflow integration | Resistance to change and steep learning curves | Comprehensive training and stakeholder buy-in |
| Regulatory and ethical considerations | Lack of standardized approval frameworks | Establish clear validation and approval pathways |
| Automation bias | Over-reliance on AI recommendations | Promote balanced human–AI collaboration |
| Explainability | Black-box nature of AI decisions | Invest in explainable AI models |
| Multi-omics integration | Need to combine histology with genomics, proteomics | Foster interdisciplinary research |
| Global implementation disparities | Unequal access to AI infrastructure | Encourage global partnerships and data sharing |
| Validation in real-world settings | Limited large-scale pilot studies | Run robust clinical trials and pilots |

AI recommendations, poses another challenge. Research by Rosbach et al. [82] highlighted the risks associated with automation bias, particularly under time pressure, which can lead to erroneous clinical decisions. Therefore, training and education on the appropriate use of AI tools are essential to mitigate these risks.

Regulatory and ethical considerations also pose significant hurdles. The lack of standardized guidelines for validating and approving AI-based diagnostic tools creates uncertainty for developers and healthcare providers [83, 84]. Regulatory bodies must establish clear frameworks to assess the safety, efficacy, and transparency of AI algorithms before they can be deployed in clinical settings [62, 85]. Additionally, ethical concerns-such as patient data privacy, accountability for AI-driven decisions, and the potential for over-reliance on automation-must be addressed to ensure responsible implementation [86, 87].

Automation bias represents another critical challenge, where clinicians may place undue trust in AI recommendations, even when they contradict their own judgment [88]. Studies have shown that under time pressure, healthcare providers are more likely to defer to AI outputs, potentially overlooking errors or misdiagnoses. Mitigating this risk requires fostering a balanced approach where AI serves as an assistive tool rather than a replacement for human expertise [89, 90]. Continuous education and decision-support systems that encourage critical evaluation of AI outputs can help reduce over-reliance.

Looking ahead, the future of AI in clinical pathology is promising, with emerging technologies poised to further enhance diagnostic capabilities. The integration of AI with multi-omics data-such as genomics, proteomics, and metabolomics-could enable more precise and personalized diagnostic approaches [91, 92]. For example, AI algorithms analyzing genetic mutations alongside histopathological features could improve cancer subtyping and treatment selection. Similarly, advancements in explainable AI may increase transparency, allowing clinicians to understand and trust AI-generated insights. The integration of AI with other emerging technologies, such as genomics and molecular profiling, holds the potential to further enhance diagnostic accuracy and personalize treatment strategies [2, 93].

To fully realize AI's potential, collaborative efforts among researchers, clinicians, policymakers, and industry stakeholders are essential. Investment in interdisciplinary research, large-scale validation studies, and real-world pilot programs will be crucial for refining AI applications. Additionally, fostering global partnerships to share data and best practices can accelerate progress while addressing disparities in AI adoption. By tackling current challenges and embracing future opportunities, the field can harness AI to revolutionize clinical pathology, delivering faster, more accurate, and equitable diagnostics for patients worldwide.

## Conclusion

The integration of automation and AI into clinical pathology represents a paradigm shift in diagnostic medicine, offering unprecedented improvements in accuracy, efficiency, and scalability. By leveraging advanced algorithms, digital pathology platforms, and high-throughput automation, AI has demonstrated remarkable capabilities in tasks ranging from tissue segmentation and cancer subtyping to prognostic prediction and workflow optimization. Case studies, such as PathChat's multimodal diagnostics and TriPath's 3D tissue analysis, underscore the transformative potential of these technologies in augmenting pathologists' expertise and addressing longstanding challenges like inter-observer variability and sampling bias. However, the successful adoption of AI hinges on addressing critical barriers, including data biases, workflow integration, regulatory frameworks, and ethical considerations, to ensure equitable and reliable implementation across diverse clinical settings.

Looking ahead, the future of AI in clinical pathology is poised for further innovation, particularly through synergies with multi-omics data, explainable AI, and global collaborative initiatives. These advancements promise to usher in an era of precision medicine, where AI-driven insights complement human judgment to deliver faster, more accurate, and personalized diagnoses. To realize this vision, sustained investment in interdisciplinary research, robust validation studies, and clinician education will be essential. By navigating these challenges thoughtfully, the field can harness AI's full potential to revolutionize patient care, transforming clinical pathology into a more dynamic, data-driven, and patient-centric discipline.

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## Conflict of Interest

None.

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