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Review Article

# A Lifecycle Framework for Digital Pathology Implementation: Integrating Infrastructure, Workflow, Regulatory Compliance, and AI Readiness for Sustainable Adoption

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## Abstract

***Background and objectives:*** Digital pathology (DP) is transitioning from an adjunct technology to an enterprise diagnostic platform in the United States. Despite accelerating clinical adoption, many laboratories face persistent barriers, including high capital and operating costs, workflow disruption, interoperability challenges, and a complex regulatory and reimbursement environment. This narrative review proposes a practical lifecycle framework for implementing and sustaining DP programs, with an emphasis on defining and operationalizing institutional artificial intelligence (AI) readiness for safe and sustainable adoption. ***Methods:*** We performed a targeted narrative review informed by searches of PubMed/MEDLINE and Google Scholar for English-language publications from January 1, 2014 through December 31, 2025. Core search concepts included DP, whole slide imaging, image management/viewing systems, laboratory information system integration, validation, reimbursement, U.S. Food and Drug Administration clearance, Clinical Laboratory Improvement Amendments oversight, College of American Pathologists accreditation, interoperability standards, cybersecurity, and AI. We supplemented database searches with reference screening and review of primary guidance and public databases from regulatory and professional organizations in the United States. We prioritized peer-reviewed literature and used web-based regulatory sources when they represented the authoritative primary reference. We also incorporated our professional experience and knowledge in DP and AI. ***Results:*** Key implementation domains span foundational infrastructure (scanners, storage/networking, and integrated image management platforms), workflow redesign across pre-analytic, analytic, and post-analytic phases, validation and quality management, regulatory compliance and accreditation, cost capture, interoperability strategy, cybersecurity and access control, education and change management, and long-term governance. We also describe an institution-level AI readiness model that can be assessed across data quality, integration, validation, monitoring, governance, and workforce capabilities to support safe clinical AI deployment. ***Conclusions:*** Successful DP implementation requires a lifecycle approach that couples technical build-out with workflow redesign and institutional governance. Early planning for compliance, interoperability, reimbursement strategy, and AI readiness can reduce implementation risk and position laboratories for sustained clinical and computational innovation.

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## Introduction

Over the past decade, digital pathology has advanced from an emerging adjunct technology to a clinically mature and increasingly integral platform across pathology laboratories in the United States. Regulatory clearance for primary diagnosis, continued innovation in whole slide imaging (WSI), the normalization of remote work, and rapid advances in artificial intelligence (AI) have together created strong momentum for adoption in both academic medical centers and community practices. While implementation varies among institutions, ongoing efforts to address reimbursement and cost considerations are expected to accelerate and broaden adoption of digital pathology.[1]

The aim of this review is to break down the implementation of digital pathology into its tangible infrastructure components—scanners, storage, image management systems (IMS), and staffing. We also explore workflow design, change management, regulatory compliance, system interoperability, cybersecurity and access control, education and training, and long-term governance across vendors and institutions. In essence, we discuss the full lifecycle of digital pathology implementation in the United States using a holistic implementation framework.

**Keywords:** Digital pathology; Whole slide imaging; Implementation; Workflow redesign; Regulatory compliance; CAP validation; Interoperability; DICOM; Reimbursement; Telepathology; Artificial intelligence; Cybersecurity.

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**Table 1. Example implementation roadmap for digital pathology (lifecycle approach)**

| Phase | Key activities | Core deliverables | Example metrics |
|---|---|---|---|
| 1. Plan & govern | Define scope/use cases; stakeholder alignment; vendor strategy; risk assessment; budgeting | Governance charter; RACI; project plan; success metrics; fallback plan | Budget adherence; stakeholder sign-off; risk log completeness |
| 2. Build & integrate | Scanner/IMS deployment; storage/network provisioning; IMS-LIS integration; identity/access setup | Validated interfaces; infrastructure runbooks; security baseline | Scan success rate; image latency; interface error rate; uptime |
| 3. Validate & train | CAP-style validation for intended uses; competency assessment; SOPs; change control | Validation report; SOPs; training records; QA plan | Concordance rate; training completion; QC defect rate |
| 4. Go-live & stabilize | Staged rollout (pilot-scale); monitor performance; support escalation; glass fallback | Go-live checklist; support playbooks; stabilization report | Turnaround time; incident rate; user adoption; rescan rate |
| 5. Optimize & scale | Workflow refinement; KPI review; expansion to new services/sites; AI enablement | Continuous improvement backlog; expansion plan; AI readiness assessment | Productivity; consult turnaround; cost per case; AI monitoring KPIs |

AI, artificial intelligence; CAP, College of American Pathologists; IMS, image management systems; KPI, key performance indicator; QA, quality assurance; QC, quality control; RACI, responsible/accountable/consulted/informed; SOP, standard operating procedure.

## Core infrastructure

Most digital pathology initiatives begin with a foundational set of infrastructure components: WSI scanners; image management and viewing platforms; scalable storage and network infrastructure; integration with the laboratory information system (LIS); formal project management and regulatory planning; and dedicated technical and operational staffing. WSI scanners digitize glass microscope slides at high resolution, producing navigable digital replicas that approximate traditional light microscopy while enabling new computational capabilities. IMS and equivalent viewing platforms organize, store, and distribute WSIs across clinical and research workflows, providing pathologists with microscope-like functionality (pan, zoom, annotations, and measurements) while enabling secure access, collaboration, and integration with enterprise systems. For cytopathology and hematopathology, where three-dimensional cellular architecture presents unique imaging challenges, the value of Z-stack support and newer extended-focus functionalities are areas of active exploration. Z-stack refers to the acquisition of multiple focal planes through the thickness of a specimen to better capture three-dimensional structures; extended-focus algorithms attempt to computationally combine focal planes into a single in-focus image.[2]

The data intensity of WSI necessitates scalable storage architecture supported by adaptable network infrastructure. Even a single digitized slide can approach the storage footprint of a full-length movie. Effective digital pathology programs typically adopt tiered storage strategies that balance performance and cost, prioritizing low-latency access for recently scanned or frequently accessed cases while archiving older material on lower-cost media. Integration between the IMS and LIS is critical, as these systems function as the backbone for accessioning, specimen tracking, workflow orchestration, reporting, and auditability. Tight LIS–IMS integration ensures accurate image–patient-context association across the end-to-end diagnostic process. These technical components must be underpinned by formal project management, change control, and compliance planning during implementation, followed by sustained technical and operational support after go-live. Dedicated project management transforms aspirational digital pathology visions into executable scope, timelines, budgets, and governance structures, coordinating stakeholders across pathology, information technology, compliance, vendors, and institutional leadership. However, simply layering digital tools onto legacy glass-based processes frequently results in parallel workflows, duplicated effort, and reduced efficiency. Without careful re-engineering, laboratories may retain manual slide handling and fragmented communication while simultaneously absorbing new tasks such as scanning, image quality control, and data reconciliation—ultimately negating anticipated benefits of digitization.

## Operational workflow design

Operational benefits should drive a digital pathology strategy for institutional growth. Common clinical use cases include primary digital sign-out, telepathology and remote consultation, second opinions, image analysis and AI applications, digital archiving, quality assurance, peer review, tumor boards, education, and research integration. Digital sign-out is a frequent goal, offering diagnostic flexibility, potential turnaround time improvement, standardized review, and seamless collaboration. Digital pathology can further strengthen quality assurance and peer review by enabling low-friction case access with robust annotation, audit trails, and longitudinal performance tracking.[3]

Research stands to gain significantly from digital pathology. Retrospective studies can leverage digital archives for rapid cohort assembly, while multicenter collaborations can use digital sharing for centralized review. Quantitative image analysis and AI development can benefit from large, well-annotated digital datasets. Clinical and research workflows can synergistically benefit each other when implementation is carefully designed and tailored to each institution's circumstances.

Despite clear workflow benefits, a formal direct-cost reimbursement process for clinical digital pathology operations in the United States remains a challenge. At present, there is no comprehensive, nationally established reimbursement framework that directly compensates laboratories for the costs associated with slide digitization, digital image management, or digital interpretation workflows. As a result, the financial justification for digital pathology adoption continues to rely primarily on indirect value propositions.[4]

Because workflow redesign is a common failure point, many laboratories benefit from a phased implementation roadmap that aligns technical build, validation, and operational change management. A practical roadmap (Table 1) typically includes: (i) scope definition and governance; (ii) in-

frastructure build and interfaces (IMS–LIS and identity/access management); (iii) validation and competency; (iv) staged go-live with defined fallback pathways; and (v) optimization and scaling with continuous monitoring. Including a concrete roadmap in project planning can reduce parallel workflows, clarify ownership across pathology and information technology teams, and make post–go-live sustainability measurable.

## Cost reimbursement and digital pathology as a business

The pathway for reporting digital pathology service costs in the United States is currently through Category III Current Procedural Terminology (CPT) add-on codes. Beginning in 2023 and expanding in 2024, the American Medical Association CPT Editorial Panel approved a series of Category III CPT codes covering the digitization of glass microscope slides across surgical pathology and cytopathology specimen types. These codes are intended to be reported in addition to existing primary pathology CPT codes when slide digitization is performed as part of clinical interpretation. However, Category III codes do not carry assigned relative value units and therefore lack nationally defined payment rates under the Medicare Physician Fee Schedule.[5] Accordingly, use of Category III codes does not result in predictable or standardized reimbursement under Medicare, and payment determinations (if any) are typically left to the discretion of local Medicare Administrative Contractors. Commercial payer policies are similarly heterogeneous, with no consistent coverage determinations or payment structures across insurers. Consequently, laboratories cannot rely on these codes to offset the substantial capital and operational costs associated with digital pathology infrastructure, including scanners, storage, IMS, and information technology integration.

Given these limitations, a strategic purpose of the current CPT code set is to generate utilization and outcomes data to support the eventual reclassification of digital pathology services into Category I CPT codes. Such a transition would require demonstration of widespread clinical adoption, established clinical utility, and evidence that the services represent a distinct and necessary component of patient care not already valued within existing pathology codes. Until that threshold is met, reimbursement for digital pathology will remain provisional and largely indirect.

Although reimbursement remains limited, quantitative business-case analyses and benchmark data provide context for when a return on investment may be achievable, particularly in higher-volume settings where digitization reduces physical slide logistics, improves workload distribution, and decreases downstream costs. A five-year projection in a large integrated health care organization estimated approximately $18 million in total operational savings after full deployment of a digital pathology system, driven primarily by productivity and laboratory consolidation effects.[6] In a large academic cancer center, implementation of full-scale digital pathology was associated with a 93–97% reduction in physical slide retrieval requests, a reported 5-year projected savings of $1.3 million, and a 1-day decrease in turnaround time for select surgical resection cases.[7] Time-and-motion studies also demonstrate substantial logistics efficiencies; for example, one laboratory modeled average savings of more than 19 working hours per day across multiple workflows after digitization.[8] These data do not replace the need for direct reimbursement but can strengthen internal business cases by translating digital pathology benefits into measurable operational metrics.

In practical terms, the absence of consistent payer reimbursement remains a significant limiting factor for digital pathology growth in the United States, particularly for smaller laboratories and community practices with constrained capital resources. Large academic centers and integrated health systems more often absorb costs in anticipation of downstream benefits such as diagnostic efficiency, workforce flexibility, telepathology, and AI enablement. Ongoing advocacy efforts by professional organizations emphasize payer engagement and policy development to better align reimbursement models with the additional technical and staffing costs of digitized workflows.[5]

## Image quality, display, and ergonomics

Patient care improvements driven by digital pathology continue to be enabled by advances in both display quality and image acquisition. Progress in consumer electronics has driven advances in clinical-grade monitor characteristics, including resolution, luminance, contrast ratio, color fidelity, uniformity, and calibration stability, translating into improved visualization of histologic detail and subtle staining patterns. High-performance displays (typically 4K or greater) are now commonplace and can support efficient digital review by reducing excessive zooming while preserving contextual awareness comparable to traditional microscopy.[9]

Color fidelity is a particular area of interest, as diagnostic interpretation can depend on nuanced staining differences. Displays with better color performance can help preserve diagnostic consistency across users and sites. Older generations of scanners and vendor-specific WSI formats can introduce variable discrepancies between glass slides and digital slides. Variability in illumination, sensor behavior, color calibration, and image processing pipelines can materially alter tissue appearance. Temporal drift, inter-scanner variability, and software updates may affect both human interpretation and AI performance. IMS can further introduce variability, particularly through inconsistent handling of embedded color profiles (e.g., Leica SVS), sometimes necessitating temporary mitigation strategies during system upgrades. Standardization through DICOM may reduce these variations and provide more consistent digitization across scanners, IMS, viewers, and institutions. By reducing pre-analytical variables, both manual morphologic interpretation and AI applications may benefit.[10]

Environmental and ergonomic factors, including ambient lighting, glare control, monitor positioning, and workstation design, first recognized in radiology, can also contribute to diagnostic consistency and user well-being. Poor ergonomics can increase fatigue, cognitive load, and musculoskeletal strain, ultimately affecting diagnostic performance. Successful digital pathology programs therefore incorporate display governance, environmental controls, and ergonomic best practices into validation and quality assurance frameworks.[11]

## Compliance and regulatory landscape

In the United States, digital pathology operates within a layered regulatory framework encompassing U.S. Food and Drug Administration (FDA) device authorization, Clinical Laboratory Improvement Amendments (CLIA) oversight, College of American Pathologists (CAP) accreditation, and state-specific laboratory laws. Multiple WSI systems have achieved FDA clearance via de novo or 510(k) pathways for primary diagnosis (Tables 2 and 3).[12]

To avoid conflating requirements, it is helpful to separate FDA authorization (which governs device marketing and intended use for scanners, viewers, and certain software) from laboratory validation and quality management require-

**Table 2. FDA-authorized digital pathology systems available as of early 2026**

| System/Product | Manufacturer | FDA basis | Regulatory notes (abridged) |
|---|---|---|---|
| Philips IntelliSite Pathology Solution 5.1 (K233204) | Philips | 510(k) | Integrated image management and viewer for primary diagnosis; validated display options include Barco MDPC-8127, Dell MR2416, and Dell U3223QE |
| Roche Digital Pathology Dx (VENTANA DP 200) (K232879) | Roche | 510(k) | Digital pathology solution including scanner and viewing workflow; validated display options include Barco MDPC-8127, Dell MR2416, and Dell U3223QE |
| Roche Digital Pathology Dx + VENTANA DP 600 (K242783) | Roche | 510(k) | Expanded scanner configuration (DP 600) within Roche Digital Pathology Dx ecosystem; validated display options as in Roche DP Dx |
| Aperio AT2 DX System (K190332) | Leica Biosystems (Danaher) | 510(k) | Whole slide imaging system for primary diagnosis; validated display includes Dell MR2416 |
| Aperio GT 450 DX (K232202) | Leica Biosystems (Danaher) | 510(k) | High-throughput WSI scanner for primary diagnosis; validated display includes Dell MR2416 |
| Sectra Digital Pathology Module 3.3 (K232208) | Sectra | 510(k) | Viewer/IMS software authorized for primary diagnosis with Leica Aperio GT 450 DX under specified display/file-format configurations per device labeling |
| HALO AP Dx (K252762) with qualified scanners (e.g., Aperio GT 450 DX or Hamamatsu NanoZoomer S360MD) | Indica Labs (HALO) with scanner partners | 510(k) | Viewer/IMS solution authorized for primary diagnosis when paired with qualified scanners and displays per device labeling |
| PathPresenter Clinical Viewer (K250968) | PathPresenter, Inc. | 510(k) | Clinical viewer authorized for primary diagnosis when used with qualified scanners and display configurations per labeling |
| Lumea Digital Diagnostic Suite Viewer+ (K242244) | Lumea, Inc. | 510(k) | Viewer authorized for primary diagnosis under specified configurations per device labeling |
| Epredia E1000 Dx Digital Pathology Solution (K241717) | Epredia | 510(k) | Digital pathology solution including scanner/viewing workflow authorized for primary diagnosis under specified configurations per labeling |

AP, anatomic pathology; DP, digital pathology; FDA, U.S. Food and Drug Administration; IMS, image management systems; WSI, whole slide imaging.

ments under CLIA and CAP. FDA clearance does not obviate the need for local validation. Under CAP guidelines, laboratories must perform intended-use–specific validation demonstrating diagnostic equivalence between digital and glass slides, typically involving at least 60 cases per application, a washout period (commonly >2 weeks), and documentation of concordance.[13] A structured comparison of key responsibilities across FDA, CLIA/Centers for Medicare & Medicaid Services (CMS), CAP, and state law is summarized in Table 4.

Recent regulatory developments further shape implementation. CMS guidance following the expiration of COVID-19 public health emergency flexibilities affirms that remote review of digital laboratory data and images may continue under an existing CLIA certificate, provided oversight and reporting responsibility remain with the primary laboratory. However, CMS explicitly distinguishes cytology, mandating CLIA certification for remote locations reviewing cytology slides after March 23, 2026. This distinction has significant

**Table 3. FDA-authorized displays used in digital pathology systems available as of April 2026**

| Monitor/Display model | Manufacturer | Regulatory basis | Notes (abridged) |
|---|---|---|---|
| Barco MDPC-8127 (K203364) | Barco | 510(k) | Standalone FDA-cleared digital pathology display; also referenced in labeling for select cleared WSI systems |
| Dell MR2416 | Dell | Specified in cleared system labeling | Display referenced in labeling for select cleared digital pathology systems (e.g., Aperio AT2 DX and other cleared workflows) |
| Dell U3223QE | Dell | Specified in cleared system labeling | Display referenced in labeling for select cleared digital pathology systems (e.g., Leica GT 450 DX, Sectra, Philips, and Roche workflows) |
| Beacon C811W/C811WT and BenQ PA27/PA27T (K233119) | Shenzhen Beacon Display Technology/BenQ | 510(k) | Standalone FDA-cleared digital pathology displays referenced in labeling for select digital pathology solutions |

FDA, U.S. Food and Drug Administration; WSI, whole slide imaging.

**Table 4. Regulatory and accreditation layers relevant to digital pathology in the United States**

| Layer | Primary scope | Examples | Laboratory responsibilities (high-level) |
|---|---|---|---|
| FDA device authorization | Medical devices and intended use (scanners, viewers/IMS, some AI SaMD) | 510(k) or de novo clearance for WSI systems; SaMD clearances for certain AI tools | Select devices for intended use; follow labeling; maintain device change control and cybersecurity with vendor updates |
| CLIA/CMS oversight | Laboratory operations, quality systems, personnel, and testing | CLIA certificate, CMS guidance for remote review; specialty-specific requirements | Maintain QMS; ensure appropriate oversight and reporting; meet remote-work/site requirements when applicable |
| CAP accreditation | Accreditation requirements and validation | CAP WSI validation guidance; checklist requirements for document control, QA, competency | Perform intended-use validation; document competency; maintain ongoing QA/monitoring and audit readiness |
| State laws | Additional state licensure and permitting requirements | California AB 2107; New York CLEP | Confirm state-specific remote review and licensure requirements for multi-site workflows |
| Privacy & security frameworks | Protection of protected health information and access controls | HIPAA/HITECH; institutional policies | Implement role-based access, audit logs, encryption, incident response, and vendor governance |

AI, artificial intelligence; CAP, College of American Pathologists; CLEP, Clinical Laboratory Evaluation Program; CLIA, Clinical Laboratory Improvement Amendments; CMS, Centers for Medicare & Medicaid Services; FDA, U.S. Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act; HITECH, Health Information Technology for Economic and Clinical Health Act; IMS, image management systems; QA, quality assurance; QMS, quality management system; SaMD, software as a medical device; WSI, whole slide imaging.

implications for telecytology workflows.[14,15]

State-level laws add further complexity. For example, California's AB 2107 aligns state law with federal CLIA by explicitly permitting remote review of digital pathology materials without separate state licensure, while New York maintains stricter state laboratory permitting requirements. CLIA-exempt states and personnel licensure laws introduce additional variability. Consequently, digital pathology implementations, particularly multi-site or remote models, should proactively assess federal, state, and local requirements to avoid compliance gaps.[15,16]

## Interoperability and standards

Interoperability underpins scalable, multi-vendor digital pathology ecosystems. Adoption of scanner-neutral IMS or standardized image formats, particularly DICOM whole slide imaging, reduces reliance on proprietary formats and supports vendor neutrality, long-term archival stability, and cross-platform viewing. Integration standards such as Health Level Seven and Fast Healthcare Interoperability Resources enable reliable exchange of case metadata between the LIS, IMS, electronic health records, and analytics platforms, ensuring accurate linkage between images, specimens, and clinical context.[10]

Vendor strategy decisions—vendor-neutral versus vendor-specific platforms—have profound implications for interoperability, AI portability, and operational complexity. Many large institutions adopt hybrid approaches, using vendor-specific solutions for regulated clinical workflows and vendor-neutral platforms for research, enterprise expansion, and AI innovation. Early architectural decisions in this domain significantly influence long-term flexibility and sustainability.

## AI

AI increasingly serves as a primary driver for digital pathology investment. Even when not immediately deployed, AI readiness should inform implementation decisions. Successful AI integration requires rigorous validation aligned with clinical workflows, ongoing performance monitoring, and robust data infrastructure.

We define AI readiness as an institution's capability to safely deploy, validate, monitor, and govern AI tools as part of clinical workflow. AI readiness is multidimensional and can be assessed across at least six domains: (i) digitization completeness and data quality; (ii) image management and LIS integration; (iii) validation/quality management and change control; (iv) computational infrastructure and storage/network capacity; (v) governance, privacy, and security; and (vi) workforce training and adoption. A practical domain-based assessment approach, with example metrics and common gaps, is summarized in Table 5.

Cytology and hematopathology illustrate both opportunity and challenge. Gynecologic cytology adopted standardized, digitization-friendly liquid-based preparations and, as a result, developed one of the earliest pathology AI ecosystems with vendor support. Non-gynecologic cytology, as well as hematopathology, continues to lag behind in AI ecosystems, largely constrained by preparation heterogeneity, three-dimensionality, and staining variability. These pre-analytical factors complicate digitization and AI generalizability, underscoring the need for standardization. Z-stack acquisition and extended-focus approaches are potential remedies but remain challenging to operationalize in routine practice due to lack of consensus on optimal use and the associated data and workflow burden.[2]

Regulatory considerations for AI in digital pathology are evolving. While many laboratory-developed tests remain regulated primarily under CLIA, AI algorithms that make diagnostic or treatment-related claims may fall under FDA oversight as software as a medical device (SaMD), in addition to CLIA/CAP laboratory requirements.[17]

The digital pathology regulatory landscape includes both FDA-cleared digital pathology platforms/viewers for primary diagnosis and FDA-authorized AI algorithms that analyze whole-slide images to provide interpretive assistance. AISight® Dx, for example, is an FDA-cleared digital pathol-

**Table 5. Practical domains for assessing institutional AI readiness in digital pathology**

| Domain | Example measures | Common gaps | Operational mitigations |
|---|---|---|---|
| Digitization & data quality | % of workload scanned for intended use; scan failure/ rescan rates; staining/slide preparation standardization | Heterogeneous pre-analytics; variable image quality; incomplete digitization | Standardize pre-analytics; QC gates; rescanning workflows; monitor drift |
| Integration & workflow | IMS-LIS linkage accuracy; context availability (case metadata, stains); user interface ergonomics | Poor metadata linkage; parallel glass/digital workflows; unclear roles | Define end-to-end workflow; interface reconciliation; clear RACI |
| Validation & change control | Local validation datasets; SOPs; documented intended use; version control | "Pilot" tools without formal validation; uncontrolled software updates | CAP-style validation; controlled rollout; release management and documentation |
| Monitoring & performance management | Prospective QA; KPI dashboards; drift detection; error/incident reporting | No monitoring plan; untracked model performance changes | Define KPIs; periodic revalidation; multidisciplinary oversight |
| Compute, storage, and network | Sufficient compute for inference; storage headroom; network latency targets | Bottlenecks at peak load; insufficient storage retention planning | Capacity planning; tiered storage; workload scheduling |
| Governance, privacy, and security | Model governance committee; PHI controls; auditability; vendor contract terms | Unclear data ownership; weak access control; limited audit trails | Role-based access; audit logging; security review; contract governance |
| Workforce & training | Training completion; competency assessment; user feedback and adoption | Low trust; variable adoption; limited informatics expertise | Training/competency; clinical champions; escalation pathways |

CAP, College of American Pathologists; IMS, image management systems; KPI, key performance indicator; PHI, protected health information; QA, quality assurance; QC, quality control; RACI, responsible/accountable/consulted/informed; SOP, standard operating procedure.

ogy image management/viewing and workflow platform intended for primary diagnosis.[12] By contrast, Ibex Galen™ Second Read™ is an FDA-cleared AI-powered digital pathology software algorithm that assists in detecting prostate cancer on whole-slide images.[12] To minimize confusion, we use the term "AI system" to refer to the algorithmic SaMD (e.g., Galen Second Read), and "platform/viewer" to refer to the underlying image management and viewing environment (e.g., AISight Dx). Practical integration strategies should be addressed during implementation planning, including scanner and file-format compatibility, definition of intended use (e.g., triage, second read, or quantitative measurement), local validation under site-specific pre-analytic conditions, user training, and post-deployment monitoring for performance drift and software updates.

In the meantime, many institutions in the United States treat limited scenarios in which AI resembles a laboratory-developed-test model. Examples include (1) internally developed AI models created and used within a single institution; (2) algorithms labeled strictly for research, quality improvement, or decision support without clinical claims; and (3) AI tools whose output is not directly reported as a diagnostic result.

## Data security, education, and governance

In the United States, digital pathology systems manage large volumes of sensitive data and must implement robust security, privacy, and access control aligned with the Health Insurance Portability and Accountability Act, the Health Information Technology for Economic and Clinical Health Act, the 21st Century Cures Act, state and local laws, and institutional governance. Role-based access, audit logging, and encryption are foundational, particularly as remote access and cloud architectures expand.

Education and cultural adoption are equally critical for sustained growth. Structured training, competency documentation, and clinical champions foster trust and sustained use. Continuous performance monitoring, covering technical uptime, image latency, adoption rates, user experience, and financial metrics, supports accountability and optimization.

Finally, mature digital pathology programs should create governance structures to oversee vendor strategy, data ownership, upgrade coordination, and exit planning. Digital pathology should be governed as a strategic enterprise clinical platform rather than a siloed departmental tool.

## Future perspectives

Several near-term developments are likely to shape the next phase of digital pathology adoption in the United States. First, broader deployment of interoperability standards (particularly DICOM whole slide imaging) may reduce vendor lock-in and facilitate multi-algorithm AI ecosystems, enterprise archiving, and cross-institutional consultation networks. Second, cloud-based architecture and scalable storage approaches are expected to mature but will require continued attention to cybersecurity, identity management, and contractual governance for data use and retention.

Third, the regulatory and reimbursement environment remains dynamic. Expanded use of Category III digital pathology CPT codes may generate utilization data supporting future valuation models; however, sustained adoption, especially in smaller laboratories, will likely require clearer payer policies and payment mechanisms that recognize the additional technical work of digitization. Additionally, regulatory requirements for remote workflows (including emerging distinctions for cytology) will influence how laboratories design telepathology and distributed sign-out models.

Finally, AI-enabled digital pathology is expected to expand from single-task decision support toward more integrated

computational pathology workflows, including quantitative biomarker assessment, risk stratification, and multimodal integration with radiology and molecular data. Institutions that operationalize AI readiness—through standardized data, robust validation and monitoring, and appropriate governance—will be better positioned to safely adopt these capabilities as they mature.

## Limitations

This review has several limitations. First, it is a targeted narrative review rather than a formal systematic review or meta-analysis, and therefore the literature retrieval and selection process, as well as the authors' knowledge, may not capture all relevant publications across the rapidly expanding digital pathology field. Second, the framework is centered on United States clinical implementation and may not fully generalize to jurisdictions with different regulatory structures, accreditation models, or reimbursement environments. Third, cost, storage, and operational efficiency estimates vary substantially by institutional size, case mix, scanner throughput, storage architecture, and local labor costs; quantitative examples should therefore be interpreted as illustrative benchmarks rather than universally generalizable values. Finally, regulatory requirements, FDA authorizations, and payer policies are evolving, and statements in this manuscript reflect publicly available information up to the time of the literature review.

## Conclusions

Digital pathology implementation extends beyond scanners and data storage. Durable success requires a comprehensive, lifecycle-oriented framework integrating infrastructure, workflow redesign, validation, interoperability, AI readiness, security, education, performance monitoring, and institutional governance. By addressing these domains proactively—and by explicitly distinguishing device authorization from laboratory validation and operational quality management—pathology departments can realize the clinical and operational benefits of digital pathology while positioning themselves for continued innovation in an increasingly data-driven diagnostic landscape.

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## Author contributions

Drafting of the manuscript (KY), critical review and editing of the manuscript (ZL). Both authors have approved the final version and publication of the manuscript.

## References

[1] Bessen JL, Alexander M, Foroughi O, Brathwaite R, Baser E, Lee LC, *et al*. Perspectives on Reducing Barriers to the Adoption of Digital and Computational Pathology Technology by Clinical Labs. Diagnostics (Basel) 2025;15(7):794. doi:10.3390/diagnostics15070794, PMID:40218144.

[2] Yao K, Shen R, Parwani A, Li Z. Comprehensive Study of Telecytology Using Robotic Digital Microscope and Single Z-Stack Digital Scan for Fine-Needle Aspiration-Rapid On-Site Evaluation. J Pathol Inform 2018;9:49. doi:10.4103/jpi.jpi_75_18, PMID:30662795.

[3] Lujan G, Quigley JC, Hartman D, Parwani A, Roehmholdt B, Meter BV, *et al*. Dissecting the Business Case for Adoption and Implementation of Digital Pathology: A White Paper from the Digital Pathology Association. J Pathol Inform 2021;12:17. doi:10.4103/jpi.jpi_67_20, PMID:34221633.

[4] Ardon O, Asa SL, Lloyd MC, Lujan G, Parwani A, Santa-Rosario JC, *et al*. Understanding the financial aspects of digital pathology: A dynamic customizable return on investment calculator for informed decision-making. J Pathol Inform 2024;15:100376. doi:10.1016/j.jpi.2024.100376, PMID:38736870.

[5] College of American Pathologists. Digital Pathology Codes (Category III add-on codes for digitization of glass microscope slides for primary diagnosis). Available from: https://www.cap.org/advocacy/payments-for-pathology-services/digital-pathology-codes. Accessed March 11, 2026.

[6] Ho J, Ahlers SM, Stratman C, Aridor O, Pantanowitz L, Fine JL, *et al*. Can digital pathology result in cost savings? A financial projection for digital pathology implementation at a large integrated health care organization. J Pathol Inform 2014;5(1):33. doi:10.4103/2153-3539.139714, PMID:25250191.

[7] Hanna MG, Reuter VE, Samboy J, England C, Corsale L, Fine SW, *et al*. Implementation of Digital Pathology Offers Clinical and Operational Increase in Efficiency and Cost Savings. Arch Pathol Lab Med 2019;143(12):1545–1555. doi:10.5858/arpa.2018-0514-OA, PMID:31173528.

[8] Baidoshvili A, Bucur A, van Leeuwen J, van der Laak J, Kluin P, van Diest PJ. Evaluating the benefits of digital pathology implementation: time savings in laboratory logistics. Histopathology 2018;73(5):784–794. doi:10.1111/his.13691, PMID:29924891.

[9] Abel JT, Ouillette P, Williams CL, Blau J, Cheng J, Yao K, *et al*. Display Characteristics and Their Impact on Digital Pathology: A Current Review of Pathologists' Future "Microscope". J Pathol Inform 2020;11:23. doi:10.4103/jpi.jpi_38_20, PMID:33042602.

[10] Herrmann MD, Clunie DA, Fedorov A, Doyle SW, Pieper S, Klepeis V, *et al*. Implementing the DICOM Standard for Digital Pathology. J Pathol Inform 2018;9:37. doi:10.4103/jpi.jpi_42_18, PMID:30533276.

[11] Krupinski EA. Human Factors and Human-Computer Considerations in Teleradiology and Telepathology. Healthcare (Basel) 2014;2(1):94–114. doi:10.3390/healthcare2010094, PMID:27429262.

[12] U.S. Food and Drug Administration. 510(k) Premarket Notification Database. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Search terms included K233119, K232208, K193054, K241717, K242244, K250968, K252762, K232202, K190332, K242783, K232879, K233204, K243391, and K241232. Accessed March 11, 2026.

[13] Evans AJ, Brown RW, Bui MM, Chlipala EA, Lacchetti C, Milner DA, *et al*. Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology. Arch Pathol Lab Med 2022;146(4):440–450. doi:10.5858/arpa.2020-0723-CP, PMID:34003251.

[14] Centers for Medicare & Medicaid Services. REVISED: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance (QSO-23-15-CLIA). 2025. Available at: https://www.cms.gov/files/document/qso-23-15-clia-revised-2025-09-23.pdf. Accessed March 11, 2026.

[15] Wadsworth Center, New York State Department of Health. Clinical Laboratory Evaluation Program Guide. 2025. Available from: https://www.wadsworth.org/sites/default/files/2025-03/CLEPGUIDE_Mar2025_FINAL.pdf. Accessed March 11, 2026.

[16] California State Legislature. Assembly Bill No. 2107 (2023-2024 Session): Clinical laboratory technology - remote review. 2024. Available at: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240AB2107. Accessed March 11, 2026.

[17] Pantanowitz L, Hanna M, Pantanowitz J, Lennerz J, Henricks WH, Shen P, *et al*. Regulatory Aspects of Artificial Intelligence and Machine Learning. Mod Pathol 2024;37(12):100609. doi:10.1016/j.modpat.2024.100609, PMID:39260776.