COLLEGE of AMERICAN PATHOLOGISTS

DIGITAL PATHOLOGY 101

Packing Your Bags for a Digital Pathology Journey

Introduction

The Digital and Computational Pathology Committee of the College of American Pathologists (CAP) is routinely asked about how to begin using digital pathology in the laboratory. General questions such as "Where do I start?" or "How do I implement a digital pathology system?" are common. Given the unique nature of each pathology group, there's no universal answer. Nevertheless, the aim of this guide is to provide a general framework for approaching such a project, along with key considerations for each stage of the process.

The guide is organized into nine sections, each covering a critical phase of a digital pathology implementation project—such as acquisition or validation—or an essential project management element like change management or ergonomics. While it doesn't cover every detail, it does give you a practical checklist to review and discuss within your organization and with the diverse array of stakeholders involved in any digital pathology initiative.

The adoption of digital pathology is rapidly transforming anatomic pathology. It improves efficiency and flexibility and opens new opportunities in how we practice our specialty—and early adopters are already experiencing substantial benefits.

On behalf of the CAP's Digital and Computational Pathology Committee, I congratulate you on your first steps into digital pathology, and trust that this guide will help you transition successfully.

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Note: References to vendors, products, or services in this section are for informational purposes only. The College of American Pathologists does not endorse, recommend, or guarantee any vendor, product, or offering mentioned.

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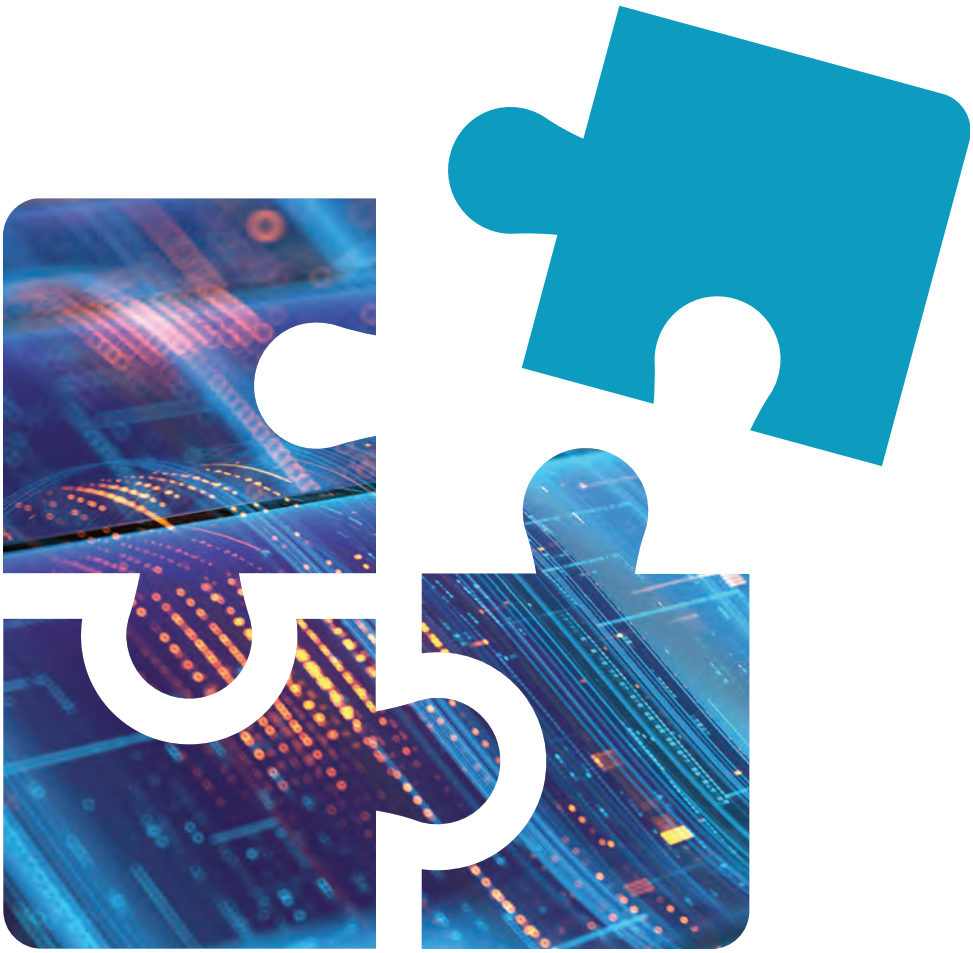
Acquisition

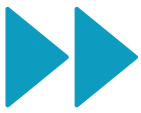


Defining the "Problem to Solve"

The first step in digital pathology is determining the problem you want to solve. While technology can be incredibly valuable, technology that doesn't solve a real problem is simply a gadget. Take an objective look at your institution, do a SWOT analysis (identify the organization's Strengths, Weaknesses, Opportunities, and Threats), and explore how the strengths of digital pathology can resolve issues that were previously difficult or impossible to solve.

A. Problem to solve: Primary diagnosis

While the goal of performing primary diagnosis digitally is commendable, it doesn't substantially improve the diagnostic workup process without the integration of AI tools. When considering the implementation of digital pathology, it's important to focus on the additional challenges that digital pathology solutions can address to enhance the diagnostic workflow.



B. Problem to solve: Logistics

Logistics become much simpler with digital pathology, as images move at the speed of your network connections, rather than at the speed of a courier. This is an especial advantage for pathology groups that aren't close geographically, both in terms of turnaround time (TAT) and convenience.

C. Problem to solve: Teaching, tumor boards, and archival storage

The use of digital slides allows much more flexibility in keeping, sharing, and displaying slides. This gives remote pathologists flexibility in presentations and teaching.

D. Problem to solve: Ease of intra- or extra-departmental consults

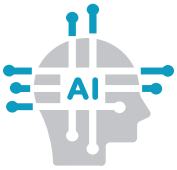
Digital pathology streamlines workflows, allowing cases to be shared with colleagues in just a few clicks. This can increase efficiency, as consultations can be performed without either party leaving their desk.

E. Problem to solve: Pathologist and/or staff efficiency

While pathologists are initially slowed during their transition to digital sign out, most find that digital slides make them more efficient in the long run. Tight integration with the laboratory information system (LIS) is key. Where LIS integration isn't immediately possible, consider other options such as barcode-assisted case assembly. Work with your image management system (IMS) vendor to explore what options are available.

F. Problem to solve: Staffing and retention

As more pathologists train with digital pathology, it becomes challenging to find staff who want to use glass slides. Digital pathology also allows for remote work, an attractive way to recruit and retain pathologists.



G. Problem to solve: AI application(s)

AI assistance for pathologists holds promise to increase efficiency and improve quality. As we move forward, AI algorithms will become an accepted, if not required, part of the diagnostic pathway.

H. Problem to solve: Remote rapid onsite evaluation of cytology

Digital pathology allows a pathologist to perform rapid onsite evaluation of cytology from their workstation, facilitating management of more cases/tasks than if they traveled to each procedure. Reliability, downtime procedures, and image quality with frozen section slides must be carefully addressed to understand the limitations and net benefits of either whole slide image (WSI) or live microscopy for deployment.

I. Problem to solve: Remote frozen sections

Like the remote evaluation of cytology, allowing a pathologist to read a frozen section remotely can increase their efficiency by removing travel time. However, downtime procedures must be developed in the event of technology failure. Again, you must fully understand the limitations and net benefits of either WSI or live microscopy for deployment.

Build Institutional and Pathologist Readiness for Digital Pathology

1. Provide awareness and knowledge

Before you begin a digital pathology implementation project, take care to understand the group's readiness to embrace change and their awareness of what digital pathology can (and can't!) do for them. This will help develop both a foundation for productive discussions and a desire for digital pathology solutions. Providing this knowledge up front may take a while, but the time invested will pay off when the group understands and wants the change to happen, rather than looking at it as being forced on them.

2. Articulate a vision and build desire

Being able to clearly communicate the vision for what a project will mean for your group—and for each person affected—is key. Professionals are generally more receptive to change when they have a clear understanding of the reasons behind it and how it will affect them. It's essential to clearly communicate the What, When, and Why on a personal level. This step takes considerable time due to the number of tailored communications needed (eg, the way in which a project affects histology is quite different from how it affects pathologists). This also requires knowing your vision and what problem you're solving for the group—remote frozen section workflows will have a hugely different effect than going to primary diagnosis for all cases.

3. Find a champion

"Champions" are respected members who lead group opinion, and having one in your corner is crucial. When implementing a huge change like digital pathology, having support from one or more of these thought leaders can help move the project forward. You should also identify group members who don't participate and work on a strategy for addressing their non-engagement before implementation begins. This period of pre-work to introduce the idea of digital pathology and how it could be used in your environment can be substantial (it literally can take years). Try looking for "low-hanging fruit" to achieve early successes, engage your contrarians, and ease the process of change management.

- Find at least one champion from the professional group, the operations group, and IT. Consider bringing on a product strategist or even fractional chief product officer to oversee the technical elements.
- Set expectations about the use of innovative technology before you even begin.
- Once the system is in place, it's too late to engage users about adoption. Ideally, your team should already be enthusiastic, having built understanding and buy-in during earlier stages. Leadership must also fully support the new system after implementation. Allowing opt-outs can undermine success, so fostering a collaborative atmosphere is crucial.

Frequently Asked Questions

Q: When implementing digital pathology, do we have to start off using it for primary diagnosis?

A: Primary diagnosis is a commendable goal, but it doesn't need to be your main objective. Digital pathology offers an array of benefits, such as greater workflow efficiency, remote slide access, and improved collaboration. Concentrate on the problems that digital pathology addresses best, which may or may not include primary diagnosis.

Q: What if our pathologists are reluctant to adopt digital pathology?

A: Leadership must require full adoption of the system; allowing opt-outs and exceptions can undermine implementation. However, adoption timelines can vary—some pathologists may take weeks or months to adjust. Providing glass slides alongside scanned images is an effective way to ease the transition.

Resistance to change is a common challenge. Monitor these concerns closely and address them during management meetings to maintain clear communication and resolution. When planning workflows, involve the stakeholders directly and document their agreement to facilitate a smooth transition.

Set a regular meeting schedule to promote effective communication and collaboration. Ensure that all team members participate and that responsibilities are shared to avoid overburdening any

one person with tasks like gathering information or drafting reports. This collaborative approach improves efficiency and team performance.

You should be ready to adjust the project's scope or redefine its approach when unique workflow obstacles arise. It's far easier to make changes early in the process than trying to do so midstream. Remain flexible and watch for any external factors that may affect the project plan.

PHASE 1

Acquisition—Key Deliverables

- **SWOT Analysis Report:** Document strengths, weaknesses, opportunities, and threats.
- **Problem Statement:** Clearly define the problem(s) digital pathology will solve.
- **Stakeholder Engagement Plan:** Identify your champions and communication strategy.
- **Initial Readiness Assessment:** Evaluate institutional and pathologist readiness.

PHASE 2

Drafting a Requirements Document

Drafting a Requirements Document

Before you go to vendors, it's essential to know your requirements. Every vendor will show their systems in the most positive light, and if you don't have clear requirements for your use-case laid out, it will be impossible to judge whether a system meets your needs.

Requirements Document Tips

Your list of system requirements does NOT need to be in technical language; in fact, it may be helpful to describe the desired *performance* rather than what 'specs' you want. However, your requirements document must contain enough detail for a vendor to give a satisfactory answer on how they'll meet the requirements.

For example, you don't need to say how many terabytes' worth of image storage are required; instead, specify that you'll need to have one year's worth of images immediately available for viewing. Let the vendors spec out their system to meet your requirements.

Hardware Requirements

When evaluating which type of whole slide image (WSI) scanner would be the right fit for your needs, it's important to understand some key features of WSI scanners. Below is a list of some key terms.

High-throughput

A high-throughput scanner can be continuously loaded or has the capacity to continuously load and scan tens to hundreds of slides. They're designed for clinical use.

> *Impact: The speed at which scans occur is not necessarily a component of high-throughput, since scan time is affected by other factors.*

Z-stacking

This term refers to capturing multiple images above and below the primary focus plane of a whole slide image. This allows the pathologist to have an analog of "fine focus," as when using the microscope.

- Differentiate scanners with **Z-stacked images**, where multiple focus planes are available individually, from **stack fusion**, also known as **focus stacking**, which combines multiple images of a specimen taken at different focal planes into a single, composite image (volumetric scanning, sparse DICOM, etc).

- Typically, **volumetric scanning** refers to inherent Z-stacking capabilities combined with 3D rendering of the stacked sections.

    Impact: Z-stacking and volumetric scanning can increase file sizes and scan time significantly depending on the number of stacks and the distance between each stack.

Scanning magnification

- WSI scanners generally have the capability to scan at 20x or 40x magnification with Z-stacking if needed. Scanning at different magnifications determines the maximum/optimal digital zoom that's available.

    Impact: Different magnifications affect file sizes and scan time, with higher magnification usually leading to larger file size and increased scan time.

EDF scanning

Some modern WSI scanners mitigate the need for Z-stacking by scanning at an "extended depth of field" (EDF), also known as focus stacking or stack fusion. As mentioned above, this combines multiple specimen images taken at different focal planes into a single, composite image. Again, this is different than Z-stacking, which provides for a fine focus-like user experience.

Impact: EDF scanning increases file size and scan times.

Barcoding

This refers to integrating barcodes for laboratory information system (LIS) workflow. It's essential that the scanner be able to read barcodes on slides associated with a case in the LIS. This allows you to automate scanning and to interface with the LIS. When the scanner reads the barcode on a slide, it downloads the associated case information from the LIS to the scanning system.

Workstations and Displays

The pathologist workstation will typically have multiple monitors, each with different characteristics—one better for viewing images, another for text, etc. Typically, one high-resolution monitor is dedicated to the WSI workflow, with additional monitors focused more on reading for LIS, EMR, and communications applications.

The workstation should also have an ergonomic design, such as dual-monitor setups for multi-modal viewing, and input devices such as an Ergopointer, a 3D mouse, a trackball, a touchpad, or a combination thereof. Experiment with a variety of devices—a standard mouse, a trackball, a joystick, or even a foot-controlled scrolling device. The correct monitor setup and pointing device will improve ergonomics for the user.

*For more details on ergonomic setup, see the **Ergonomics Considerations** section.*

High-resolution monitors (minimum 27", ≥4K resolution, and color-calibrated) are essential for an effective setup. Diagnostic-grade monitors, which are typically more costly than consumer models, do provide a slight technical benefit—mainly that they may be "pre-certified" for a given WSI system. While monitors can be of any size or resolution, it's best to stay reasonable; any advantages of very large screen sizes or 8K vs. 4K are often mitigated by the ergonomic and functional difficulties of scrolling across large distances or decreased text size.

Note: All monitors need to be assessed for color calibration.

Graphics processing units (GPUs)

Graphics processing units (GPUs) to enhance image rendering are key to a more effective setup. A GPU with enough memory and monitor outputs to connect to the desired viewing system(s) is

an essential component of a WSI viewing system and will determine the pathologist workstation design, maximum number of monitors, and their resolution.

Cabling

Proper attention must also be given to the cabling of high-definition connections, including HDMI and DisplayPort. Cable specifications affect maximum supported resolution and color fidelity, especially when compared to legacy technologies that may not support current performance standards.

Servers and Computer Infrastructure

High-performance servers

Effective AI requires high-performance servers for image analysis. These days, that kind of processing power most often comes from cloud-based systems rather than local (aka *on-premises* or *on-prem*) servers. Server requirements are determined by workflow needs, research-oriented work, and the sophistication of the laboratory's technological environment. However, as storage costs decrease and processing power increases, we expect changes in this area in the near future. The question of cloud vs. on-premises computing will continue to evolve rapidly, so it's important to ensure that any choices you make today can easily be revisited.

Note: Regardless of the infrastructure you choose, consider what support your team will have to ensure resource scalability. Cloud architect training for the IT staff responsible for infrastructure choices is important. Many computing environments are transitioning to software as a service (SaaS) plus cloud-based processing and storage. The determining factors in these choices today are total cost of ownership, processing power, and communication speeds.

Software Requirements

Digital Pathology Viewers

During the acquisition process, you'll need to decide between FDA-cleared/CE-marked software and laboratory-developed tests (LDTs) for primary diagnosis. The digital pathology viewer is typically integrated into vendor-provided solutions, although there are independent viewers that can

be used across different scanning solutions. A closed FDA-approved system will typically include a specified viewer, monitor, and GPU. If you vary this setup, the resulting "open" system methodology will then inherently require you to validate the integrated devices at the level of an LDT.

Viewing system features should include the basics of zooming, panning, image rotation annotation, measurement (linear and freeform), tissue architecture detection, and side-by-side case review. Another useful feature is "slide tracking," which shows what areas of a slide have been viewed and at what magnification. While most viewing systems include the basics, the user's subjective experience and satisfaction will still vary from system to system. As you evaluate different systems, the pathologists who will be using them need to consider how these functions affect each system's ergonomics and efficiency.

Planning Your Image Management System (IMS)

Repository and architecture

A centralized repository for WSI that supports both DICOM and non-DICOM formats is important. Although this approach reflects a current industry trend, not all systems have fully adopted DICOM. Additionally, if the WSI technology stack involves multiple vendors, it may not be practical to consolidate all images into a single repository.

Note: DICOM wrappers are software applications that add DICOM headers to data from radiology modalities that's not natively in DICOM format. The data can then be interpreted by the IMS and included in patients' imaging studies, making it easily accessible to the physician interpreting the study.

An IMS that has a truly **vendor-neutral architecture (VNA)** may allow for a storage solution that supports different WSI scanners. This requires careful analysis, planning, design, and implementation.

Vendor-neutral architecture

Vendor-neutral architecture may be the best option for some organizations, as it allows multiple user groups (eg, pathology, radiology, cardiology) or image viewing systems to access the image archive and storage. As this requires additional work to implement, consider carefully whether this is required for your institution.

Image management functions

Effective management of image data requires a system that supports several key functions. You must be able to view and process images and to store both the processed and unprocessed versions. You should also be able to manage version-controlled annotations and incorporate linked clinical metadata to ensure comprehensive data handling and analysis.

Essential functions include metadata indexing, prefetching, caching, and lifecycle management. Unfortunately, few systems relate tissues scanned to diagnosis or data retention. This is a significant limitation of data retention rules, case selection, and even pre-scanning.

Laboratory information system (LIS) integration

Most of the metadata associated with WSI comes from LIS data and pathologist interpretation, which is typically unstructured textual data. It will be necessary to have bidirectional communication with the LIS and connectivity to structured pathology data.

Bidirectional communication with the LIS using HL7 or FHIR standards is essential for a WSI system. This interface lets LIS data populate the IMS and WSI system with user input. This not only improves efficiency, but LIS data can drive many downstream processes and workflows. To date, however, few sophisticated workflows are driven by LIS data—even for basic tasks like using tissue type and diagnosis to determine tissue retention time, a simple use case.

Artificial intelligence (optional but increasingly critical)

AI tools can be used for triage, quantification, quality control, etc. One of the drivers for implementing WSI is the development of image analysis technology that leverages AI to read pathology images. These tools provide *quantitative analysis* of tissue features (eg, cell counting) and *qualitative assessments* that are useful for QA activities. They can also perform routine assessments such as stain quality and tissue artifacts, along with medical features such as differential diagnosis.

Image analysis tools should be integrated into the viewer; they may also be available as validated third-party plugins. While the workflow will vary with the system, and will continue to evolve, it's essential to make applying image analysis activities to tissue images as user-friendly as possible. The more efficient and integrated these tools are, the more readily they'll be used. Keep in mind that applying image analysis tools across different vendor platforms requires validation, and mixed-platform solutions can lead to unexpected results.

Case tracking

Using barcode-based case and asset tracking and workflow orchestration is now the expectation in the modern pathology lab. Such tracking is essential to assess volume, throughput, and TAT on scanner platforms.

Bandwidth and latency

The minimum recommended upload speed is 1 Gbps, with a preferable range of 2.5–10 Gbps for optimal performance. Similar speeds are recommended for downloading, viewing, and performing AI inference (minimum 1 Gbps, recommended 2.5–5 Gbps). You may need bandwidth of 10 Gbps or higher in environments where there are many simultaneous users (eg, academic hospitals) to ensure uninterrupted access. For high-throughput scanning labs, which include central laboratories or academic centers, the requirements are even more demanding—upload and download speeds of 10 Gbps or higher are typical. In some cases, dedicated fiber links or even 100 Gbps uplinks may be needed to effectively support the infrastructure.

- Internal bandwidth of ≥1 Gbps (fiber preferred) and low latency for real-time viewing.
- Should specify upload and download speeds (also need at least 1 Gbps for image upload to cloud or on-prem).

A dedicated network segment isolates scanner-to-IMS communication from the general hospital LAN, enabling a direct, optimized data path between scanners and storage/IMS without interference from unrelated network traffic (eg, EHR access, email, or internet browsing). A dedicated network segment can also be used to isolate FDA-approved systems from unplanned updates and security patches that may invalidate FDA certification.

- Consider dedicated network segments for scanner-to-IMS communication.

Wide Area Network

Virtual private network (VPN)

A VPN allows access to networks. A VPN may also contain the specialized applications that enable users to enter firewalled systems for telepathology/remote case viewing and to access the WSI image servers or other IT resources the business provides. Please note that while a VPN does

provide appropriate security, it can also downgrade your network bandwidth and will increase the complexity of the user login, so these approaches to system access need to be thoroughly tested.

- Secure VPN tunnels for remote diagnostics, subject to regulatory compliance.

Support for cloud-hybrid configurations

Cloud-based and hybrid architectures offer flexibility and enhanced access control. Cloud-based applications eliminate the need for on-premises servers, while integrated security services reduce the need to rely on a VPN. These solutions can also provide back-end storage for image data. A hybrid model typically either combines cloud-based applications with on-premises storage, or local application hosting with cloud storage. In today's environment, this approach is an excellent choice because of its adaptability.

Content Delivery and Caching

During implementation, consider potential performance gains from edge caching or prefetching images from servers to local storage to optimize loading of large WSIs. While this can improve performance in some cases, carefully consider the cost and overhead. Similarly, in cloud environments, load balancing across servers helps maintain high availability and performance.

Data Storage Considerations

File format and long-term readability

- Adopt open standards, such as the Committee on Open Medical WSI (COM WSI) format or other recognized DICOM WSI to ensure future accessibility.
- Avoid proprietary file formats when possible to reduce the risk of vendor lock-in.
- Ensure metadata standards (eg, DICOM attributes) are preserved for future interoperability.
- Plan for technology obsolescence—periodically validate file readability as systems evolve.

Retention policies

- Align with regulatory and accreditation guidelines (CAP, CLIA, FDA) or institutional policy. It may not be necessary to retain digital images if glass slides are retained, although guidelines are evolving.
- Keep clear distinctions between clinical vs. research archives (may have different retention needs).
- Consider jurisdictional variations (eg, US vs. EU GDPR considerations for data retention and deletion).
- Establish policies for retaining both primary and derivative data (WSI, annotations, AI outputs).

Scalability

- Infrastructure designed for petabyte-scale storage with modular expansion (scale-out storage solutions)
- Hybrid storage strategies (on-premises, cloud, or hybrid models)
- Support for tiered storage (hot, warm, cold) to optimize performance and cost
- "Future-proof" by planning for anticipated data growth (eg, expansion of digital pathology beyond current subspecialties)

Backup and disaster recovery

- Create robust backup strategies, including air-gapped, immutable, or WORM (Write Once, Read Many) backups.
- Establish geographic redundancy for critical data (off-site replication or cloud-based DR solutions).
- Craft clear recovery time objectives (RTO) and recovery point objectives (RPO) aligned with clinical needs.
- Hold regular disaster recovery drills to validate recovery procedures and timelines.
- Document roles, responsibilities, and escalation pathways for disaster recovery scenarios.

Performance considerations

- Ensure low-latency access to active datasets to support clinical turnaround times.
- Optimize storage architecture for high-throughput image retrieval (parallel I/O, fast network connectivity).
- Implement load balancing strategies to handle concurrent user access, especially in high-volume centers.
- Evaluate and monitor performance metrics (read/write speeds, network bandwidth use).
- Integrate with content delivery networks (CDN), or edge computing where applicable, to improve speed.
- Ensure compatibility with AI workloads that may require rapid access to large datasets.

Data Storage Options

Storage Type	Description
Short-term (active) storage	Short-term storage is used for recently created or regularly accessed data, such as scans from within the previous three months. Fast-access SSDs or high-performance NAS systems safeguard low latency and ensure quick retrieval. • These systems are ideal for active workflows where performance is essential.
Redundancy and failover capabilities (RAID 6 or better)	Redundancy ensures that data remains accessible even if one or more drives fail. RAID 6 offers protection against two coinciding disk failures, making it appropriate for high-availability environments. Systems with failover capabilities automatically switch to the backup. • This will minimize downtime.
Long-term (archival) storage	Long-term, or archival, storage is for infrequently accessed data that still needs to be retained. This includes historical records and compliance documents as well as other important materials and data. It's optimized for cost efficiency rather than speed. Data is typically stored in durable, low-cost media like tape or cloud-based object storage.
Tiered storage options (such as object storage)	Tiered storage systems automatically move data between different types of storage based on usage patterns. Frequently accessed data stays on the faster, more expensive media, while infrequently accessed data is moved to the slower, less expensive storage options. Object storage is ideal for archival storage because it's scalable and cost-effective. • Tiered storage systems support metadata and a simpler retrieval process.

Security Measures and Data Protection

Topic	Considerations
Data encryption	Encrypt data at rest and in transit (TLS 1.2 or higher).
Access	Implement role-based access control and multi-factor authentication.
Auditability and logging	• Set up comprehensive audit trails for scan acquisition, access, and diagnosis. • Integrate with hospital security information and event management systems.
Compliance	• Ensure compliance with HIPAA, GDPR, FDA CFR Part 11, or equivalent regulations. • Conduct regular vulnerability scanning and penetration testing.

System Integration Requirements

Topic	Description
Laboratory information system (LIS)	• Integrate directly with LIS for case accessioning and case status updates. • Synchronize case data (case ID, patient demographics, specimen details) in real time. • Support barcoding and specimen tracking systems to align physical and digital workflows. • Automate data exchange for quality control, turnaround time reporting, and KPIs. • Facilitate LIS-driven launching of WSI viewer from within case management screens.
EHR integration	• Launch pathology reports or WSI viewer from EHR systems in a context-aware manner. • Implement FHIR-based interoperability to support longitudinal patient data. • Enable bi-directional exchange of structured data (diagnoses, CPT codes, SNOMED codes). • Embed pathology reports (including images) directly into the clinical workflow. • Trigger notifications or alerts in EHR when results are available.
Radiology PACS and enterprise imaging integration	• Facilitate cross-disciplinary image viewing (both radiology and pathology). • Integrate with a vendor-neutral archive (if best from an enterprise point of view). • Harmonize metadata standards across PACS and digital pathology archives (IHE profiles, DICOMweb). • Install multi-disciplinary tumor board tools that access both radiology and pathology images. • Align enterprise image lifecycle management policies (retention, archival, deletion).
Single sign-on (SSO) and directory services	• Integrate with Lightweight Directory Access Protocol (LDAP), Active Directory (AD), or Security Assertion Markup Language (SAML)-based SSO platforms. • Map role-based access controls (RBAC) through directory services. • Implement federated identity management across health system affiliates or partners. • Create audit trails linked to enterprise identity for compliance and security monitoring. • Integrate with multi-factor authentication (MFA) where applicable.

Based on your requirements document, send out requests for proposals (RFP) for the following image pathway products:

- WSI scanners
- Image storage systems
- Image display systems

Note: Some vendors will have solutions for multiple parts of the image pathway. Using a single vendor for multiple products has both advantages and disadvantages. Just as every pathology group is unique, addressing different challenges and different ecosystems, so no one solution will be the "best" for everyone.

Frequently Asked Questions

Q: How do we choose the correct scanner capacity?

A: Scanner capacity can range from one to several hundred slides, and you need to consider both *volume* and *throughput*. Both factors are influenced by the histology laboratory's workflow, the capacity for digital storage, your network bandwidth, and the pathologists' expertise and workload. Keep in mind that manufacturers base their throughput calculations on a "standard" slide, which usually means tissue covering one 15mm x 15mm area. If your slides have more tissue, your scanning times will be higher than the given specifications.

Q: Should we scan at 20x or 40x magnification?

A: This depends on your institution's use case and standard practices. If your pathologists routinely work at 10x or 20x objective power and rarely go higher, then it may make sense to routinely scan at 20x. However, whole slide images scanned at the highest available magnification are preferable for some applications, so balance your current needs with future requirements, especially for machine learning/artificial intelligence (ML/AI) and research.

Q: What are the most common image quality issues during implementation?

A: Common image quality issues come from both human and scanner error.

- Issues due to poor quality histology practices can include bubbling from coverslip mistakes, insufficiently clean slides (dirt, dust, mounting media), and tissue that extends beyond the coverslip. The laboratory can address these issues by following the same quality practices implemented in histology for slides examined with light microscopy.

- Issues related to the scanners can include incomplete tissue capture and image stitching errors. The manufacturer should address these issues.

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PHASE 2

Drafting a Requirements Document—Key Deliverables

- **Requirements Specification Document**
  - Hardware requirements (scanners, monitors, GPUs)
  - Software requirements (IMS, viewer, LIS integration)
  - Network and bandwidth specifications

- **RFP Package:** Requests for proposals for scanners, IMS, and display systems
- **Integration Plan:** LIS/EHR connectivity and interoperability requirements

PHASE 3

Determine the Return on Investment (ROI)

Once your digital pathology vision is established, your stakeholders are aligned, and the vendor proposals have been received, you'll have the data you need to determine the return on investment (ROI) for your project. ROI in this context isn't just about direct cost savings—it's about understanding what problems you're solving and whether the investment aligns with the value they create.

Cost avoidance: What can you stop paying for?

A common misconception is that digital pathology eliminates most traditional histology costs. Many core processes remain unchanged. ROI typically comes from solving related challenges—such as reducing courier expenses, enabling remote work, improving turnaround times, reducing pathologist travel to remote sites, or consolidating subspecialty review.

Cost of the system

This is usually the most straightforward part of the ROI equation. Vendor proposals should clearly define the costs, but dig deeper. Ask about "hidden" expenses—such as licensing, integration, or support. Push vendors to provide a complete picture, especially for critical add-ons not included in the base offering. Some of this can be incorporated in the service level agreement (SLA).

Cost of new workflows

Digitization often requires new processes. Engage your subject matter experts (SMEs) to be sure you're aware of any additional staffing needs—for example, for histology quality control, digital slide routing, or IT administration. While some tasks may add costs, others can offset with savings—such as being able to eliminate glass slide shipping.

Drafting a budget and implementation plan—major cost categories to consider

Slide Scanners

Capital expense: Scanner hardware

Use case: Primary vs. secondary scanners; redundancy planning

Cost range:

- High-throughput scanners (slide capacity 300–450): $250K–$625K
- Low-throughput/backup scanners (slide capacity 4–6 to 20–60): $20K–$200K

Recommendation: To avoid sunk-cost errors, consider purchasing the scanner last, after you've defined the workflow and established support. You can even wait until you're almost in production; that allows you to maximize the scanner demonstration as part of the workflow, rather than in isolation.

Servers and IT Storage

Cost of storage: The cost of storage management is a significant operational expense that should be part of your annual budget. This amount includes several key components—including hardware, infrastructure, and software—which incur up-front purchase costs as well as ongoing maintenance and licensing fees. You must also plan for the cost of eventual replacements, along with the expenses associated with storage media, personnel, and utilities. The physical space required in a data center contributes to these costs, as do the necessary investments in data backup and replication, business continuity, and disaster recovery efforts. Additionally, as technology evolves and/or capacity needs increase, your data may need to be migrated, which will add to the financial considerations.

Storage architectures and factors to consider

Storage type	Considerations
Vendor-hosted cloud	• Fully managed solution provided by scanner or image management system (IMS) vendor. • Simple to deploy with a minimal internal IT burden. • Can be expensive over time, especially due to data egress charges and premium support tiers.
On-premises storage	• Requires initial capital investment in hardware, power, cooling, and IT support. • Offers low variable cost over time. • Less scalable; future upgrades may require reinvestment.
Group-sponsored or institution-controlled cloud	• Lease storage directly from a cloud provider (eg, AWS, Azure, Google Cloud). • Offers greater control and potential cost savings compared to vendor-hosted options. • May require internal DevOps or cloud architecture expertise.
Hybrid storage models	• Combines on-premises for short-term/high-speed access with cloud for long-term archiving. • Can optimize cost vs. access speed. • Requires storage management

Strategies to optimize storage management costs

There are several strategies available to minimize the cost of storage. One approach is to reduce the number of isolated storage silos, thus fostering a more integrated system. It's crucial to implement a scalable storage management design, to reduce reliance on proprietary components, and to adhere to established standards for archiving and integration. It's also wise to purchase storage based on your expected volume/growth needs over the next 12–24 months, as costs for storage generally decrease over time. Finally, use your applications' performance requirements—especially data retrieval times—as a guide when selecting subsystems and associated media. These strategies will help you better manage storage costs while maintaining efficiency and effectiveness.

Viewer vs. image management system (IMS)

- **Viewers:** Basic slide review only, often bundled with scanners

- **IMS:** Full workflow support—case management, laboratory information system (LIS) integration, AI tool integration, workload balancing, internal/external consultation

- **Costs**
  - **One-time:** Scanner ingestion, LIS integration, user training
  - **Recurring:** Tiered subscriptions by slide volume or user license

Tip: Choosing Between Viewer and IMS

If you have a strong LIS/EMR with digital modules, a viewer might suffice. Otherwise, an IMS offers scalability and multi-institutional support.

LIS interfaces

Critical for primary diagnosis. If in-house capability exists, build internally. Otherwise, vendors may provide or recommend integration support.

IT Support and Consulting

Roles and functions

Role	Function
IT director	Strategic oversight
Cloud architect	Storage architecture and data access optimization
Software engineer	Application and interface development
Project manager	Coordination of timelines, milestones
Product manager	Alignment of implementation with institutional needs

Tip: Assign Roles Strategically

Assign tasks appropriately. Do not misuse SMEs for project management or vice versa—it wastes time and money.

New hardware for pathologists and other users

- Monitors
  - For FDA-cleared solutions, monitor specifications are strict. However, for many implementations, medical-grade monitors may not be necessary.

- Computers
  - Ensure they have sufficient RAM, processing power, and discrete graphics cards.
  - Avoid machines with integrated/onboard graphics for diagnostic use.

Ongoing and recurring costs

- Licenses
  - Budget for both initial and renewal fees.
  - Consider concurrent users vs. named user licenses—plan for scaling.

- Maintenance and support
  - Includes software upgrades, replacement planning, and vendor support.
  - Critical for clinical use; may be bundled in vendor contracts or require separate budgeting.

- Storage
  - Align whole slide image (WSI) retention with the problem you're solving.
  - Keeping WSI for many years may not be cost effective. Although the CAP still requires glass slide retention, it doesn't require digital image retention (as of publishing this guide)

Calculate the ROI for the problem you're solving

After estimating all direct and indirect costs, compare them to the anticipated value. ROI may not be strictly financial—it could be strategic. In fact, a negative ROI in dollar terms might still justify implementation if it solves a critical operational or clinical problem.

Questions to think about when calculating ROI

- Does this improve quality, safety, or access?
- Does it enhance recruitment, retention, or reputation?
- Are you enabling new revenue streams or strategic partnerships?

If the answer to any of those questions is "yes," the investment may be worth it. Even when the ROI doesn't appear positive on strictly financial grounds, an investment that provides broader benefits can still be supported.

Examples of return on investment

- Revenue generation: Partnering with CROs or AI companies for image sourcing
- Workforce flexibility: Remote access and workload balancing
- Operational efficiency: Faster turnaround time, fewer courier runs
- Clinical quality: Use of ML tools for quality assurance
- Recruitment & retention: Attracting modern-minded talent

Final step: Gaining budget approval

Digital pathology touches many teams—pathologists, histotechnologists, IT, operations, compliance. Your budget and implementation plan must reflect cross-functional input and shared commitment.

Once approved, be realistic in your promises. It's better to under-promise and overdeliver. Focus on pursuing high value, achievable wins early in the process, which will help you build momentum.

Frequently Asked Questions

Q: What are "hidden costs" of digital pathology that we need to consider?

A: There can be significant expenses beyond scanners, software, and storage. One such expense is data transfer fees, particularly when using cloud-based applications. Many cloud providers charge you to transfer data out (egress fees); these charges can rapidly exceed the storage fees if you frequently retrieve large volumes. Your internet service provider may also limit your data. While these caps are becoming less common, they may increase your overall expense if there are surcharges for exceeding them, especially in rural areas or other situations with limited connectivity.

Q: What if our ROI calculation is negative?

A: A negative ROI may still justify implementation if it addresses critical operational or clinical issues. Consider the overall strategic value of digital pathology, including improvements in quality, safety, access, employee recruitment and retention, and new revenue streams. This value can often outweigh a non-profitable ROI, reinforcing the benefits of adopting digital pathology.

PHASE 3

Determine the Return on Investment—Key Deliverables

- **Cost Avoidance Analysis:** Identify expenses that can be eliminated.
- **System Cost Summary:** Detailed vendor proposals, including hidden costs.
- **New Workflow Cost Assessment:** Staffing, training, and process changes.
- **Budget and Implementation Plan:** Major cost categories and strategies.
- **ROI Calculation:** Compare costs to anticipated value (financial and strategic).
- **Budget Approval Documentation:** Cross-functional input and shared commitment.

PHASE 4

Change Management

Change management is key when implementing digital pathology. A project management office—or someone with expertise in project management and change management theory—can help you by tracking milestones and keeping all stakeholders on track.

It's equally important to recognize that digital pathology is a cultural shift, not just a technical upgrade. For example, switching from glass slides to digital viewing changes how pathologists sign out cases, consult with colleagues, and even teach trainees.

- **Engage a project manager to guide the process**, track milestones (such as scanner installation, validation study completion, and first clinical cases), and align stakeholders across pathology, IT, and hospital leadership.
- **Create urgency** by clearly communicating the disadvantages of staying analog. Examples can include delayed second opinions or the inability to work remotely.
- **Focus on quick wins to build momentum**—such as piloting digital review for frozen sections or tumor boards—before full primary diagnosis.
- **Build a coalition of early adopters**. Identify respected pathologists and technologists who are enthusiastic about digital tools and can influence others.
- **Communicate a clear vision**, such as "Within one year, 90% of surgical pathology slides will be scanned and available digitally."
- **Remove barriers by streamlining login processes**, optimizing scanner workflows, and ensuring that IT support is readily available.
- **Reinforce the new workflows by integrating digital viewing** into daily sign-out, training new hires on digital systems from day one, and celebrating success stories to make the change stick.
- **For resource-restricted groups (capital and/or personnel):** Try piloting a small institution or hospital center, iterating the improvements, then scaling to larger institutions/hospitals.

Highlight "What's in it for me?" for each group

When introducing digital pathology, it's crucial to tailor messaging to the different stakeholder groups by clearly answering the question, "What's in it for me?" When you highlight the personal and professional benefits, it increases buy-in and reduces resistance.

Storage architectures and factors to consider

Group	Benefits
Pathologists	• Faster access: Read slides from anywhere—no need to wait for glass slide delivery. • Improved collaboration: Consult colleagues across the hall (or around the world) with only a few clicks. • Enhanced diagnostics: Compare current and prior cases side-by-side using digital tools (eg, annotation, measurement, and AI imaging resources) to improve accuracy. • Work flexibility: Review cases remotely, give second opinions, or even provide on-call coverage without returning to the hospital. • Future readiness: Remain relevant as pathology fully matures into the digital workspace.
Histology and laboratory staff	• Reduced physical handling: Fewer slide deliveries and manual handoffs, minimizing the risk of breakage or misplacement. • Clear prioritization: Digital systems automatically flag STAT cases, reducing confusion about urgent work. • Skill development: New technical skills in scanner operation, image quality control, and digital workflows will enhance career growth. • Recognition: Early adoption positions lab staff as visible contributors to innovation in patient care. • Expanded use cases: Histology-based applications such as positive control monitoring, IHC validation, and lot-to-lot comparisons, etc.
Administrative staff	• Operational efficiency: Easier scheduling of tumor boards and consultations with predictable digital workflows. • Better metrics: Better tracking of turnaround times and productivity, which improve reporting and resource planning. • Reduced physical storage needs: Digital archives mean less space needed to store physical slides, lowering costs.
Clinicians and other customers	• Faster diagnosis and consultation: Shorter turnaround times for pathology reports speed up clinical decision-making and patient care. • Improved access to expertise: Easier expert consultations without the need to ship physical slides. • Enhanced multidisciplinary care: The seamless display of pathology images during tumor boards and case discussions strengthens collaborative treatment planning. • Patient education: Greater potential for improved communication and compliance. • Clinical innovation: Accelerated access to clinical trials and development of new targeted therapies, digital biomarkers, and other approaches using digital image data.

Develop a communication plan

Communication is essential to a digital pathology implementation project. You must have a clear vision and a well-defined message of change—and no matter how it may feel, it's impossible to over-communicate it.

Change can be unsettling—especially a change that alters daily workflows—so it's crucial to communicate early, often, and across multiple channels. Emphasize the rationale and the widespread benefits within and beyond the lab and the institution.

Suggestions for internal communications

Pathologists and laboratory staff
Provide regular updates through meetings, emails, and bulletin boards. Share project milestones (eg, "First scanner installed," "Validation study launched") and highlight early success stories. Host Q&A sessions where staff can openly voice their concerns and have them addressed.

Leadership and administration
Tie progress summaries to institutional goals (eg, faster turnaround times, enhanced remote consultation capabilities, operational efficiency). Reinforce how digital pathology supports strategic initiatives like expanding outreach services or improving patient care.

Training and support
Communicate available resources clearly—such as training sessions, quick reference guides, and IT support contacts—so staff know how to get help when they need it.

Suggestions for external group communications

Clinicians and referring physicians
Proactively inform key clinical teams about how digital pathology will improve service (eg, faster results, easier image sharing for tumor boards). Set clear expectations for timing and any changes to the reporting process.

Patients
If digital pathology supports telepathology consultations or outreach services, consider crafting patient-facing messaging that reassures them about quality, security, and benefits ("State-of-the-art diagnostics using digital imaging technology").

External partners and institutions
If your lab handles external consultations or outreach cases, notify them of the transition. Emphasize any enhancements in turnaround time, access to subspecialists, or new service offerings.

Frequently Asked Questions

Q: How do we handle the initial productivity drop?

A: As with any change, there will be an adjustment period, often with a temporary drop in productivity. Remind staff that productivity will return to previous levels—and may even improve—once the transition is complete. This reassurance can help build confidence about the future of digital pathology in your lab.

PHASE 4

Change Management—Key Deliverables

- **Change Management Plan:** Milestones, stakeholder alignment, and project tracking
- **Communication Plan:** Messaging for each stakeholder group ("What's in it for me?")

PHASE 5

Validation

When implementing digital pathology, it's important to develop guidelines that medical directors can adopt across institutions and CLIA labs. This ensures uniformity across validations, sites, and users. The validation process is not only a chance to be sure your system works as expected, but is a great way for pathologists to become comfortable with this new technology.

Instrument validation

Instrument validation is defined as the process by which an instrument is demonstrated to show acceptable concordance with a comparator gold standard method. For whole slide images (WSI), >95% intraobserver concordance must be demonstrated for the same pathologist comparing review of traditional glass slides and review of digital images.

- CAP guidelines (ANP.12500 – ANP.12700) require at least one pathologist to review a minimum of 60 cases that represent the spectrum of intended applications per WSI instrument.
- H&E-stained sections of fixed tissue, frozen sections, immunohistochemistry, cytology, and hematology are considered separate applications of WSI.
- If the spectrum of case types is increased after validation is complete, an additional 20 cases representative of the additional application are required.

Validation workflow options

Step	Option 1	Option 2
Case selection	60 cases are selected and scanned for digital review.	60 cases previously reviewed by the pathologist (≥2 weeks old) are retrieved.
First review	The pathologist reviews **digital images** and renders diagnoses.	The **original glass diagnoses** (from ≥2 weeks ago) are recorded.
Second review	After a **two-week washout**, the pathologist reviews the **same cases on glass slides** and renders diagnoses again.	The **same slides are scanned** and reviewed as **digital images** by the same pathologist.
Variability assessment	A different staff member calculates **intraobserver variability.**	A different staff member calculates **intraobserver variability**.

Note: Significant changes to the WSI system require a full 60-slide validation by at least one pathologist. It isn't necessary to separately validate each individual component.

Deployment

There are no current guidelines on how to confirm that a user is sufficiently familiar with an instrument to use it on patient samples. Each institution should, therefore, craft its own recommendations based on its specific needs. Here is a sample recommendation for medical directors:

- Every pathologist will train on every digital pathology instrument at least once (if a new site is deploying the same scanner, software, and hardware on which a pathologist has previously received training, repeat training is NOT required).
- Every pathologist expected to deploy the instrument will complete a focused evaluation to demonstrate competency to the satisfaction of the medical director (recommendation: 10–20 cases at >95% intraobserver concordance; if <95% is observed, the number of reviewed cases should be increased as needed to achieve >95% concordance).
- If a pathologist participated in WSI instrument validation, additional cases for evaluation are not required.

Establish validation and quality assurance protocols for diagnostic reliability

When implementing digital pathology for diagnostic purposes, your institution should establish validation and quality assurance protocols to ensure diagnostic reliability, accuracy, and patient safety. These protocols should include the following:

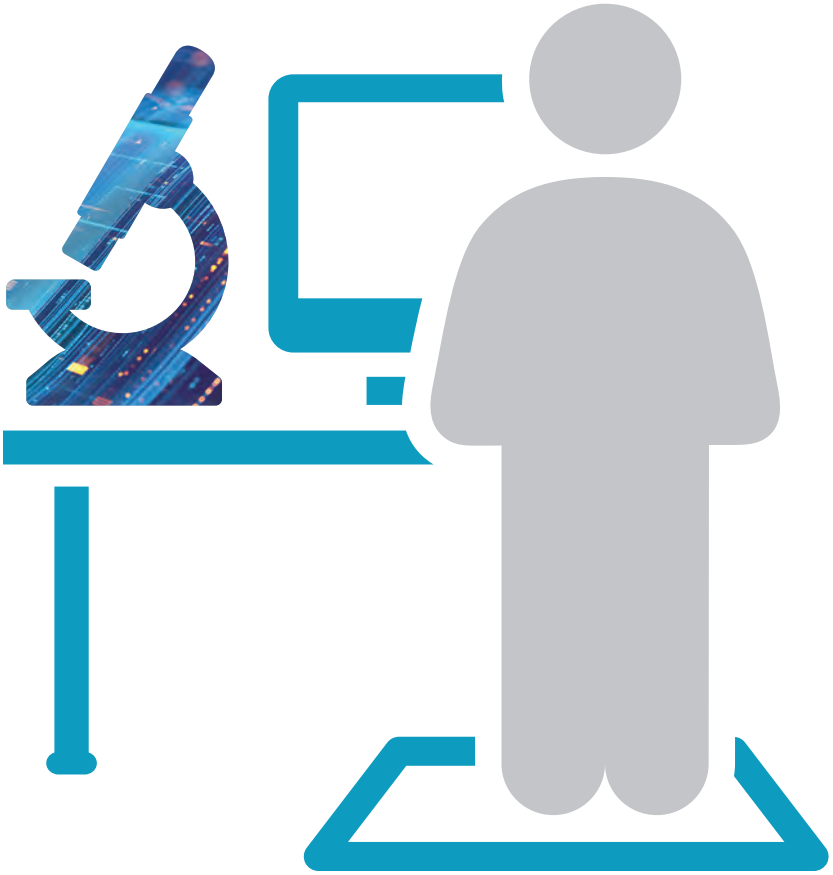
- Diagnostic equivalence
- Regulatory compliance
- Hardware and software controls
- Error detection and reduction
- Change management
- Change control policies

PHASE 5

Validation—Key Deliverables

- **Validation Protocols:** Instrument validation workflow and guidelines
- **Case Selection and Review Documentation:** Track cases and intraobserver variability
- **Deployment Readiness Checklist:** Training and competency demonstration
- **Quality Assurance Protocols:** Diagnostic reliability, regulatory compliance, error detection, and change management

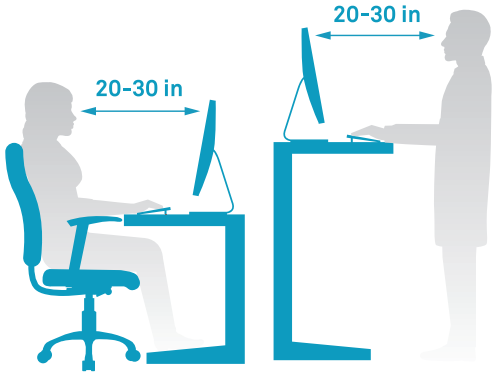
Ergonomic Considerations



Workstation design

- Workspace layout: Design workstations that promote neutral body postures and minimize repetitive motions while also allowing for an efficient workflow.

Neutral body posture support



- Monitor height and distance: Monitors should be positioned directly in front of the user, with the top of the screen at or slightly below eye level. They should be ~20–30 inches from the user's eyes to reduce strain while allowing for easy slide viewing.
- Chair and desk adjustability: Use adjustable chairs with lumbar support and armrests to promote a neutral seated posture. Consider incorporating sit-to-stand desks.
- Keyboard and mouse position: Input devices should be at elbow height with forearms parallel to the floor. Use ergonomic mice and low-force keyboards to minimize repetitive stress.

User customization

- Allow pathologists to personalize their workstation layouts (eg, slide viewer orientation [horizontal vs. vertical], display colors, and background themes) for optimal contrast and comfort.
- Conduct regular ergonomic assessments and gather user feedback to improve setups. Provide training on ergonomic practices and their importance in daily workflows. Teach pathologists efficient visual search patterns to enhance diagnostic accuracy and reduce fatigue.

Integration with sign-out workflow

- Functional zoning of the work area: This method divides up a workspace into categories to best support "reach economy"—ensuring that the most-used tools are within easy reach, minimizing stretching or twisting.
  - Primary zone: For digital slides and reporting interfaces (eg, laboratory information system [LIS] or voice dictation software)
  - Secondary zone: For communication tools (chat, email), clinical data, reference images
  - Tertiary zone: Storage for infrequently used items (paperwork, accessories)

Monitor setup

Single Monitor Setup (Basic or Limited-Space Configuration)

While this approach is simple, easier to set up, and has fewer cables to manage, it also leads to frequent window-switching (between the viewer, LIS, and clinical data). It also results in an increased cognitive load and thus has the potential for missed information. Invest in an ultra-wide monitor (34”+) or large 4K display to allow multiple side-by-side windows.

Dual Monitor Setup (Recommended Standard)

In the dual monitor setup, one monitor can be used for the digital pathology slide viewer (eg, Aperio, Philips, Sectra) while the second monitor can be used for the LIS, EMR, notes, or clinical images. While this setup can still require window resizing and swapping, it does provide better task separation, reduces the need to toggle windows, and mimics the traditional workflow. The ideal solution is to use two monitors of matched resolution and size (eg, two 27” 2560x1440 displays or better).

Triple Monitor Setup (Power User Configuration)

This construction is ideal for high-throughput environments, academic centers, or subspecialty work. Monitor 1 is used for the full-screen slide viewer, monitor 2 is for LIS, EMR, and pathology reports, and monitor 3 is used for reference images, side-by-side comparisons, or additional tools. Pro: This setup allows maximum flexibility and supports educational overlays, comparisons, and live consultations. Con: It requires more space, power, and GPU capacity, while also having the potential for clutter or distraction if not well-organized.

Tip: Multi-Monitor Setups

Align the primary monitor (usually the slide viewer) at eye level directly in front of the user. Place the secondary monitor(s) at a slight angle to reduce neck rotation. Match brightness and color calibration across monitors for consistency. Use monitor arms or stands to maintain optimal viewing distance (20–30 inches).

Optimizing multi-system use

- **Seamless screen transitions:** Match the monitor arrangement with the natural gaze pattern—ie, digital slide viewer in the central monitor; LIS and clinical notes on side monitors. Use consistent software placement and hot keys across sessions to reduce cognitive load.
- **Integrated voice dictation or auto-text tools:** These tools reduce keyboard use, help the user focus on the screen, and support more efficient case documentation.
- **Breaks and exercises:** Encourage regular breaks using the 20–20–20 rule (every 20 minutes, take a 20-second break to look at something 20 feet away) to alleviate eye strain and prevent fatigue.

Environmental optimization

Lighting and Glare Control

- Implement adjustable lighting to reduce glare and eye strain, ensuring the best viewing environment for digital slides.
- Use indirect, dimmable lighting to reduce screen glare.
- Use monitor hoods or anti-glare coatings if needed.
- Avoid overhead fluorescents; consider ambient or task lighting with color temperatures between 4000K–5000K (similar to daylight).

Noise Control

- Provide a more effective work environment by reducing interruptions and auditory distractions. Use sound-dampening materials (acoustic panels) on the walls and/or ceiling. Noise-canceling headphones (especially useful during complex case sign-out) or sound-proofed sign-out spaces can help reduce external noises.

Ergonomic Mouse Options & Configuration Tips

When selecting ergonomic input devices for digital pathology, you need to consider personalized factors such as hand size, preferred grip style, and specific workflow requirements.

- **Side Buttons:** Side buttons can be mapped to "Advance/return to previous cases," "Open clinical data," and "Trigger quick macros" (eg, "next slide").

- **Smooth Panning:** Lower mouse sensitivity or enable pointer acceleration settings to enhance glide feel.

- **Software Installation Constraints:** If workstations are shared, it's better to install mice with onboard memory (gaming mice) and avoid those that need custom drivers (eg, vertical mice).

Note: References to vendors, products, or services in this section are for informational purposes only. The College of American Pathologists does not endorse, recommend, or guarantee any vendor or offering mentioned.

Mouse Type	Pros	Cons	Comments
Standard mouse (basic three-button layout)	Familiar and universally compatible, typically includes left, right, and center scroll-click, sometimes includes side buttons (can be mapped for navigation).	Not ergonomically optimized, often lacks customizable features, high sensitivity (DPI) can lead to jittery cursor movements in slide viewers.	Considerations for digital pathology: Adjust DPI to 600–1600 for smoother panning, use side buttons to advance/reverse cases, avoid very high sensitivity (eg, 2400+ DPI) which can cause cursor instability in pathology software.
Simplified gaming mouse with onboard memory	Onboard memory stores user profiles (DPI, macros)—no software installation required. Portable for plug-and-play across multiple workstations, DPI settings easily toggleable (commonly 400–1600 DPI range), side buttons customizable for workflow shortcuts.	Still looks like a gaming device; may be too advanced for some users, some require initial setup on a PC with software before deployment.	Ideal for rotating users or shared environments where installation of software is restricted
Vertical mouse (eg, Evoluent Vertical Mouse)	Promotes natural handshake posture, which reduces wrist pronation and strain. Available in left- and right-handed versions, programmable buttons (varies by model), best for users with wrist strain, repetitive stress injury, or carpal tunnel.	Requires driver/software for customization (must be installed per workstation), slight learning curve, some jitter reported in high-resolution slide viewers if sensitivity is not tuned properly.	
3DConnexion SpaceMouse Pro + CADMouse	3D navigation for panning/zooming can mimic microscope movement. CADMouse has high-precision tracking, customizable buttons (including side buttons). SpaceMouse allows for subtle slide manipulation (pan/tilt/zoom).	More costly; SpaceMouse can be too advanced unless heavily used, and not all pathology viewers support 3D mouse input natively.	Ideal for advanced users wanting tactile microscope-like control and for power users in high-volume digital pathology labs.

Mouse Type	Pros	Cons	Comments
Kensington Expert Mouse (trackball)	Stationary device reduces wrist and arm movement, large trackball allows for smooth, precise cursor control, programmable buttons and scroll ring for navigation.	Takes time to get used to, not portable, less effective for users needing fast, sweeping cursor movement.	
ProtoArc Trackpad (Gesture Pad)	Touch-based control using hand gestures, gesture customization possible through Windows settings (eg, two-finger swipe to change cases), minimal wrist strain.	Gesture accuracy varies, requires users to adjust to touchpad-based navigation, not ideal for pixel-level precision work.	

PHASE 7

Training

Training of all affected groups is a key to success. However, the first step is to understand who needs to be trained, and to what depth. Allow every group—especially pathologists—plenty of time to feel comfortable with the workflows and tools prior to requiring that they be used. Additional recommendations:

- Ensure that the entire workflow is mapped out and each group has training appropriate for their tasks.
- Train early to get people comfortable with the change; also plan for "just-in-time" training to refresh skills immediately before going live.
- Set up a "playground" environment for all users to try out their tasks prior to production.
- Document the training from the start. This documentation is important for many regulators.

Every pathologist is different—some will be very comfortable with digital sign-out after a few weeks of training. Others won't feel comfortable until they've worked for several months in parallel, looking at both the digital images and the glass slides. At the beginning of the project, have frank discussions about the expectations for migrating to digital pathology, then stick to those expectations.

Frequently Asked Questions

Q: What are the biggest challenges encountered in private practice implementation?

A: The main challenges in that setting are the high initial investment, difficulty reorganizing the lab workflow to include the scanning steps, and the limited availability for pathologists to engage in the initial learning phase.

Q: How important is laboratory information system (LIS) integration?

A: LIS integration is critical for efficiency and functionality in digital pathology. You must set up bidirectional communication with the LIS using established standards to populate the image management system (IMS) with data, enable barcode-based tracking, etc.

Q: What ongoing quality assurance is needed post-implementation?

A: To be successful, you need to implement daily quality control and monitoring of both pre-imaging and imaging factors, in addition to the mandatory initial validation. Craft a quality control plan and apply a formal change control policy for any system updates.

PHASE 8

Go Live

Cutover vs. Hybrid (Digital + Glass) Workflow Considerations

There is no “best” way to approach the transition. Some groups prefer moving certain workflows or specialties to digital sign-out while temporarily keeping others on glass slides. Others find it easier to switch everyone from glass to digital at once (ie, the “big bang”) as part of a single change management plan.

Hybrid workflows—in which some pathologists or specialties in of a pathology group use digital images, while others use glass—may cause duplication of effort for the histology and slide distribution staff. Be sure to consider all viewpoints while planning for cutover.

Having and following a clear, agreed-upon cutover plan will reduce both confusion and risk. Although it will be tempting to grant exceptions as the go-live date approaches, setting clear expectations from the start will limit both such requests and the resulting confusion.

PHASE 9

Sustainment and Growth

Once your project has gone live, communicating and celebrating the success is vital to keep all stakeholders engaged. When you communicate the win to everyone involved, the entire group can take pride in what's been accomplished.

Quality assurance

The new digital pathology workflows will change how a group functions. You can assess the effectiveness of these new workflows by monitoring predefined quality metrics both before and after implementation. Consider also looking at new metrics to ensure that things are working as desired. Don't be afraid to change workflows to improve performance.

Ensure you have a change control policy

This policy should be a formal process (SOP) which ensures that any changes are introduced in a controlled and coordinated manner. It should include methods for a formal change request with impact assessment (define changes as minor and major). A proposed change should follow the following timeline: initiation, impact assessment, review and approval, implementation (validation, training, or requalification, etc), verification, and then closure.

Having a formal process in place will eliminate the confusion of multiple changes going into effect without proper communication, training, or documentation. A sample change control template is included in Appendix B.

Establish a governance committee to oversee clinical validation, SLAs, and change control processes

Setting up a multidisciplinary governance committee for clinical digital pathology adoption is an essential step to maintain reliability, regulatory compliance, and operational stability. The committee would be responsible for the following, all of which support sustainability and scalability:

- Designing the validation study
- Determining required service level agreements (SLAs) for all system components (scanners, viewers, storage, IT infrastructure, laboratory information system [LIS] integration, etc)
- Implementing a formal change control policy that would approve and document all changes
- Regulatory and legal compliance

Change Control vs. Change Management

Change control:

A formal, regulated process used primarily in regulated industries (like pharmaceuticals, medical devices, GLP/GMP labs) to review, approve, implement, and document changes to systems, processes, or products

Purpose: To ensure product quality, data integrity, and compliance with regulatory standards (eg, FDA, EMA, ISO)

Typical contexts: Quality management systems (QMS), laboratory SOPs and instruments, validated software and IT systems, clinical trial procedures, manufacturing equipment

Key characteristics: Highly documented and traceable, often part of a quality management system; focused on minimizing risk to product/process/data integrity. Includes formal risk assessments, approvals, verification, and closure

Change management:

A broader concept that refers to the structured approach for ensuring that changes are smoothly and successfully implemented in an organization—covering people, processes, and technology

Purpose: To support people through transitions, align stakeholders, and ensure that the business or organizational effect is positive

REFERENCES

1. Hansen MT. Ten ways to get people to change. *Harvard Business Review.* 2012.

2. Kotter JP. *Leading Change*. With a new preface by the author. Boston, MA: Harvard Business Review Press; 2012.

3. Hanna MG, Ardon O. Digital pathology systems enabling quality patient care. *Genes Chromosomes Cancer.* 2023;62(11):685 697. https://doi.org/10.1002/gcc.23192

4. Bruce C, Prassas I, Mokhtar M, Clarke B, Youssef E, Wang C, Yousef GM. Transforming diagnostics: the implementation of digital pathology in clinical laboratories. *Histopathology*. 2024;85(2):207 214. https://doi.org/10.1111/his.15178

5. Cheng CL, Azhar R, Sng SHA, Chua YQ, Hwang JSG, Chin JPF, Tan PH. Enabling digital pathology in the diagnostic setting: navigating through the implementation journey in an academic medical centre. *J Clin Pathol*. 2016;69(9):784 792. https://doi.org/10.1136/jclinpath-2015-203600

6. Chetty R, Johnson EJ. The management of implementing a digital pathology workflow. *Diagn Histopathol*. 2023;29(9):420 423. https://doi.org/10.1016/j.mpdhp.2023.06.010

7. Fraggetta F, L'Imperio V, Ameisen D, Carvalho R, Leh S, Kiehl TR, Eloy C. Best practice recommendations for the implementation of a digital pathology workflow in the anatomic pathology laboratory by the European Society of Digital and Integrative Pathology (ESDIP). *Diagnostics*. 2021;11(11):2167. https://doi.org/10.3390/diagnostics11112167

8. Koefoed Nielsen H, Kidholm K, Frederiksen MH, Mikkelsen MLN. Expectations and experiences among clinical staff regarding implementation of digital pathology: a qualitative study at two departments of pathology. *J Imaging Inform Med*. 2024;37(5):2500 2512. https://doi.org/10.1007/s10278-024-01087-w

9. Lujan G, Li Z, Parwani AV. Challenges in implementing a digital pathology workflow in surgical pathology. *Hum Pathol Rep*. 2022;29:300673. https://doi.org/10.1016/j.hpr.2022.300673

10. Montezuma D, Monteiro A, Fraga J, Ribeiro L, Gonçalves S, Tavares A, Macedo Pinto I. Digital pathology implementation in private practice: specific challenges and opportunities. *Diagnostics*. 2022;12(2):529. https://doi.org/10.3390/diagnostics12020529

11. Schwen LO, Kiehl TR, Carvalho R, Zerbe N, Homeyer A. Digitization of pathology labs: a review of lessons learned. *Lab Invest*. 2023;103(11):100244. https://doi.org/10.1016/j.labinv.2023.100244

12. Evans AJ, Brown RW, Bui MM, Chlipala EA, Lacchetti C, Milner DA Jr, Pantanowitz L, Parwani AV, Reid K, Riben MW, Reuter VE, Stephens L, Stewart RL, Thomas NE. Validating whole slide imaging systems for diagnostic purposes in pathology: guideline update from the College of American Pathologists in collaboration with the American Society for Clinical Pathology and the Association for Pathology Informatics. *Arch Pathol Lab Med*. 2022;146(4):440 450. https://doi.org/10.5858/arpa.2020-0723-CP

13. Zarella MD, Bowman D, Aeffner F, Farahani N, Xthona A, Absar SF, Parwani A, Bui M, Hartman DJ. A practical guide to whole slide imaging: a white paper from the Digital Pathology Association. *Arch Pathol Lab Med*. 2019;143(2):222 234. https://doi.org/10.5858/arpa.2018-0343-RA

14. Rojansky R, Jhun I, Dussaq AM, Chirieleison SM, Nirschl JJ, Born D, Fralick J, Hetherington W, Kerr AM, Lavezo J, Lawrence DB, Lummus S, Macasaet R, Montine TJ, Ryan E, Shen J, Shoemaker J, Tan B, Vogel H, Waraich PS, Yang E, Young A, Folkins A. Rapid deployment of whole slide imaging for primary diagnosis in surgical pathology at Stanford Medicine. *Arch Pathol Lab Med*. Published online July 8, 2022. https://doi.org/10.5858/arpa.2021-0438-OA

15. Glover AM, Whitman GJ, Shin K. Ergonomics in radiology: improving the work environment for radiologists. *Curr Probl Diagn Radiol*. 2022;51(5):680 685. https://doi.org/10.1067/j.cpradiol.2022.03.001

16. Sundaragiri KS, Shrivastava S, Sankhla B, Bhargava A. Ergonomics in an oral pathology laboratory: back to basics in microscopy. *J Oral Maxillofac Pathol*. 2014;18(suppl 1):S103 S110. https://doi.org/10.4103/0973-029X.141341

17. Lee MH, Schemmel AJ, Pooler BD, et al. Radiology workflow dynamics: how workflow patterns impact radiologist perceptions of workplace satisfaction. *Acad Radiol*. 2017;24(4):483 487. https://doi.org/10.1016/j.acra.2016.08.027

18. Krupinski EA. Human factors and human computer considerations in teleradiology and telepathology. *Healthcare (Basel)*. 2014;2(1):94 114. https://doi.org/10.3390/healthcare2010094

19. Sudin E, Searjeant M, Partridge G, et al. Digital pathology: the effect of experience on visual search behavior. *J Med Imaging (Bellingham)*. 2022;9(3):035501. https://doi.org/10.1117/1.JMI.9.3.035501

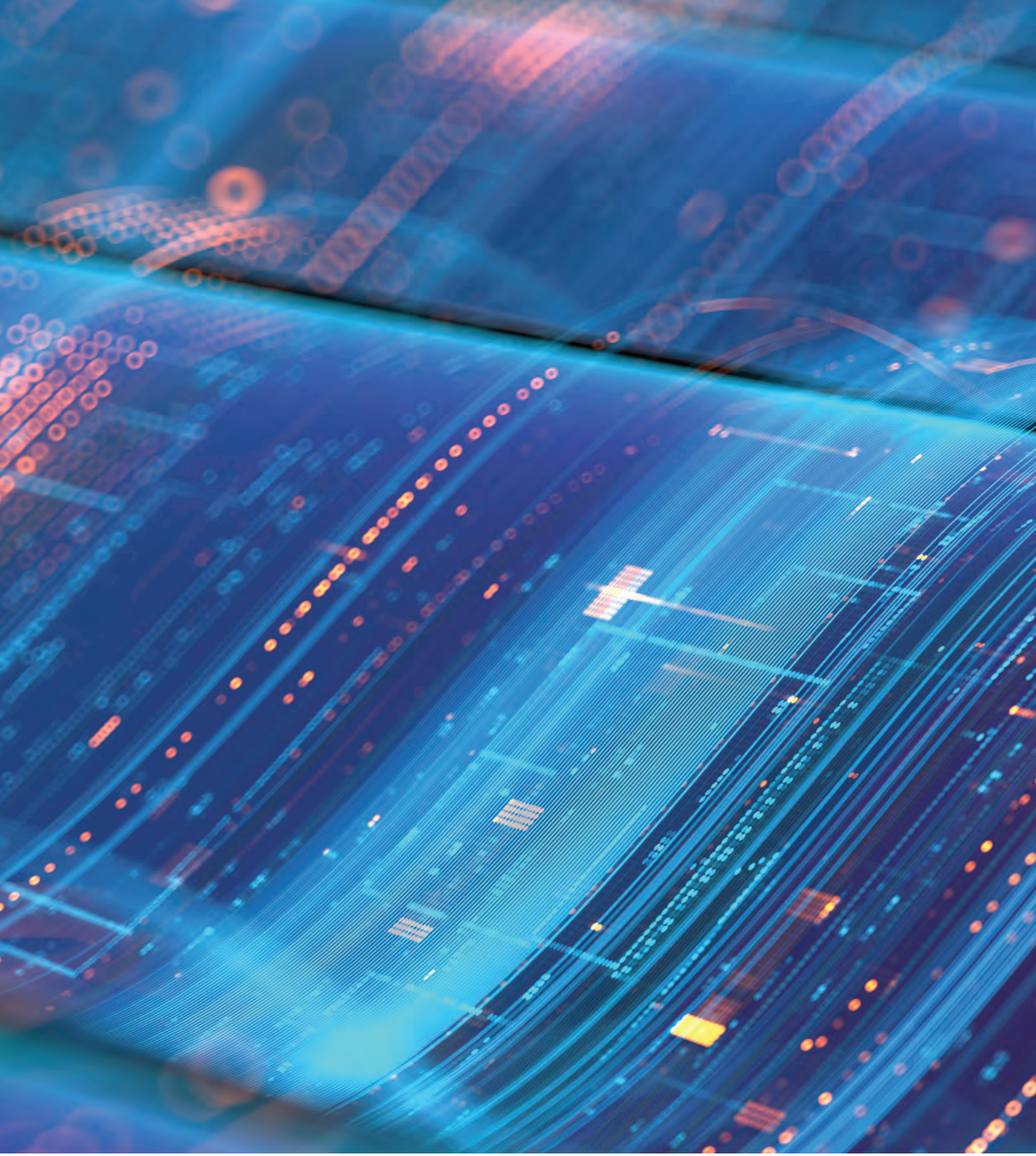
20. Lopes A, Ward AD, Cecchini M. Eye tracking in digital pathology: a comprehensive literature review. *J Pathol Inform*. 2024;15:100383. https://doi.org/10.1016/j.jpi.2024.100383

21. Society for Imaging Informatics in Medicine. *From strain to strength: the ergonomic edge for radiology and pathology professionals*. Webinar. July 17, 2025. Accessed June 30, 2025. https://siim.org/webinar/from-strain-to-strength-the-ergonomic-edge-for-radiology-and-pathology-professionals/

22. Society for Imaging Informatics in Medicine. *The Stanford pathology informatics experience*. Webinar. Accessed June 30, 2025. https://siim.org/webinar/the-stanford-pathology-informatics-experience/

23. Society for Imaging Informatics in Medicine. *Tuning your tools—getting the most out of your PCs*. Webinar. Accessed June 30, 2025. https://siim.org/webinar/tuning-your-tools-getting-the-most-out-of-your-pcs/

24. Society for Imaging Informatics in Medicine. *Pathology + DICOM: a picture perfect pairing*. Webinar. Accessed June 30, 2025. https://siim.org/webinar/pathology-dicom-a-picture-perfect-pairing/



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