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Digital Pathology Transformation:

A Guide to Digital Pathology Solution Selection

Technology selection is a vital part of the digital transformation process. Our aim is to demystify adoption by providing a framework that helps provide clarity and confidence to successfully shift from glass to digital.

Preparing for the Journey

Every lab is different, and technology selection for the digitization project must meet the unique needs of the organization, as well as the pathologists. It should address the goals for a digital pathology practice now and in the future.

Delivering new value to patients and laboratories and improving the pathologists' experience requires adapting the pathology practice by introducing modern and innovative technology solutions. At the same time, meeting changing business needs requires retooling departmental processes with technology that will drive powerful confidence and efficiency gains for pathologists and laboratory operations and provide patients with high-quality and timely diagnosis. Given the magnitude of the investment the laboratory will make when going digital, and the many vendor and technology choices available in the market, having a strategic approach and knowing what to look for in the technology before conducting the search will help streamline the decision-making process, mitigate risk associated with the large capital investment and accelerate the buying cycle.

The following sections will help any organization define a technology selection strategy, develop key considerations to guide that selection, provide an in-depth look at the components required to select a complete digital pathology solution, and help provide the basis for further actions.

To start, in order to ensure the success of the digitization project, it is essential to establish clear goals to address projected and future use cases. The following are essential first steps when considering technology selection:

Align With Department Goals

Align the selection of the digital pathology system with the department or organizational goals and priorities for the project. Plan a solution that provides functionality to address short, mid- and long-term scenarios.

Understand Current Work Requirements

Personnel requirements, workload and workflows that apply to the projected use cases must be fully understood. Compare the current with the future state and consider technology that delivers the highest impact in the areas undergoing digital transformation.

Anticipate Future Needs

Ensure that technology selection supports the organization as it evolves and has the potential for scaling to support higher case volume, additional locations, growing teams, and existing and emerging new technologies.

Check Regulatory Status

Decide if regulatory clearance is required to support the implementation of the designated use cases. Check for FDA status in U.S. and European CE Mark for in vitro diagnostics, for example.

Building a Plan for Technology Selection

The selection of a technology ecosystem will be specific to each organization. Several general considerations are applicable to component selection for the so-called "pixel pathway." All digital pathology systems include:

Image management and viewing software platform

Whole slide imaging scanner

Monitors

Some of these considerations may be familiar as they are similar to other laboratory system selections. Others are more specific to the introduction of a new digital pathology system. The following steps may be helpful to keep in mind while conducting due diligence on possible options.

Research Vendor Options

- Get exposure to potential leading vendors and perform comparative assessments.
- Understand the company, its tenure, track record and product profiles.
- Review websites and online documentation to compare specifications of the companies' technologies, including features and functionality.
- Inquire about instrument/software availability, frequency of product updates and projected lifespan of the hardware
- Consider a vendor who can become a long-term partner and is invested in customer success. Look for commitment, experience, trust and a consultative approach to the relationship.

Demos

- Request company presentations and technology demos from the leading vendors of the scanner equipment and software being considered.
- Ensure the rationale for the digitization project and the use cases are clearly articulated in discovery calls so vendors can properly address specific needs.
- Research the technology being evaluated and come prepared with questions.
- Invite the right team members into the group to help assess the technology.
- Request more than one demo if necessary—particularly if questions remain unanswered. Demos may seem fast and not cover all the grounds in the initial call.

Build a Request for Proposal (RFP)

- RFP should align with project goals.
- Send RFPs to the most qualified vendors and review the responses with internal stakeholders.
- Inquire if the features needed are available out of the box, require customization or are part of a planned future update.

Obtain References

- Obtain two or three reference laboratories with deployments in similar clinical settings. Perform on-site visits, if possible.
- Reach out to colleagues who have worked with the selected systems and/or ask vendors for contact information.
- Ask questions about the technology in a real-life setting, gather input on reliability and quality of the product/s, customer responsiveness and support.
- Inquire about the pathologists' satisfaction with the new digital workflows.

Request an Evaluation

- Perform an on-site, hands-on formal evaluation with the most qualified vendor/s—this is a critical task in the decision-making process.
- Test the scanner being considered (or the currently available options) and the commercially available version of the software together in the laboratory, preferably using the laboratory's own local histology laboratory material, if feasible.
- Define use cases for a customized environment and set success criteria.
- Include a sufficient number of cases addressing various specialties, specimens of various complexities (biopsies, excisions) and stain types.
- Involve the right team members for the hardware and software evaluations.
- Gather input from pathologists of different specialties or backgrounds testing the image management software.

Estimate Costs

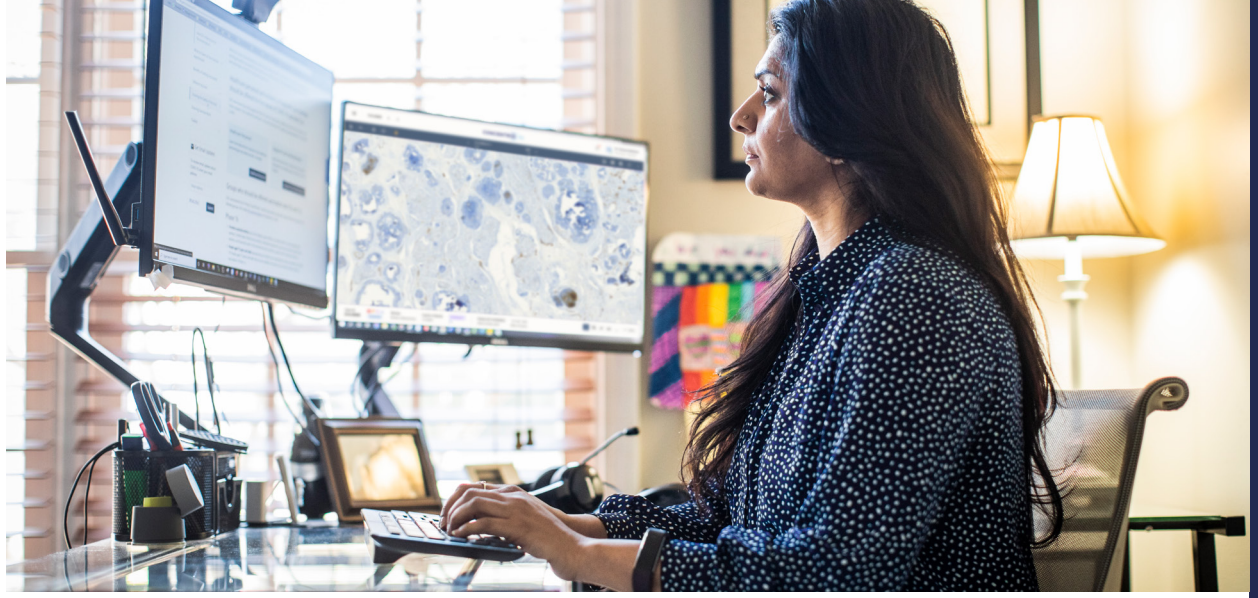
- Obtain quotes and get an estimate of pricing as early as possible. Incorporate into the budget discussions of the business plan.
- Determine if there are any additional associated costs; for example, those incurred at the time of implementation or with potential software upgrades.
- Understand professional services required for the implementation, such as integration with existing laboratory systems and infrastructure, personnel training, etc.
- Consider alternatives to a straight purchase transaction. Partner with vendors to establish "Center of Excellence" conditions where scaled discounts may be offered in exchange for evaluation or validation of emerging technology. Such a partnership, where the lab serves as a reference site, may be an excellent option.
- Involve the contracting department as needed for negotiations.

Ensure Ongoing Customer Support

- Review the various levels of service under a Service Level Agreement (SLA) and installation, warranties, education and training requirements.
- Understand the post-sales support, responsiveness and hours of operation, typical service/maintenance issues and the annual maintenance contracts.
- Consider remote access feasibility to provide efficient service and quicker resolution of software issues.
- Consider additional value-added items to support transition to digital pathology (for example, digital transformation consultative services).

Evaluating Software Platforms

Choosing the right software is the most important part of the technology selection process. It is critical that it should be done first as it will guide the selection of additional digital pathology solution components.



Traditionally referred to as an image management system (IMS), the modern software platform is much more than that—it is the primary technology that will power the modern pathology laboratory. A software platform that sits at the center of a laboratory will address organizational goals and help achieve the vision of the digitization process by improving laboratory operations now and addressing the future needs of a computationally enabled practice.

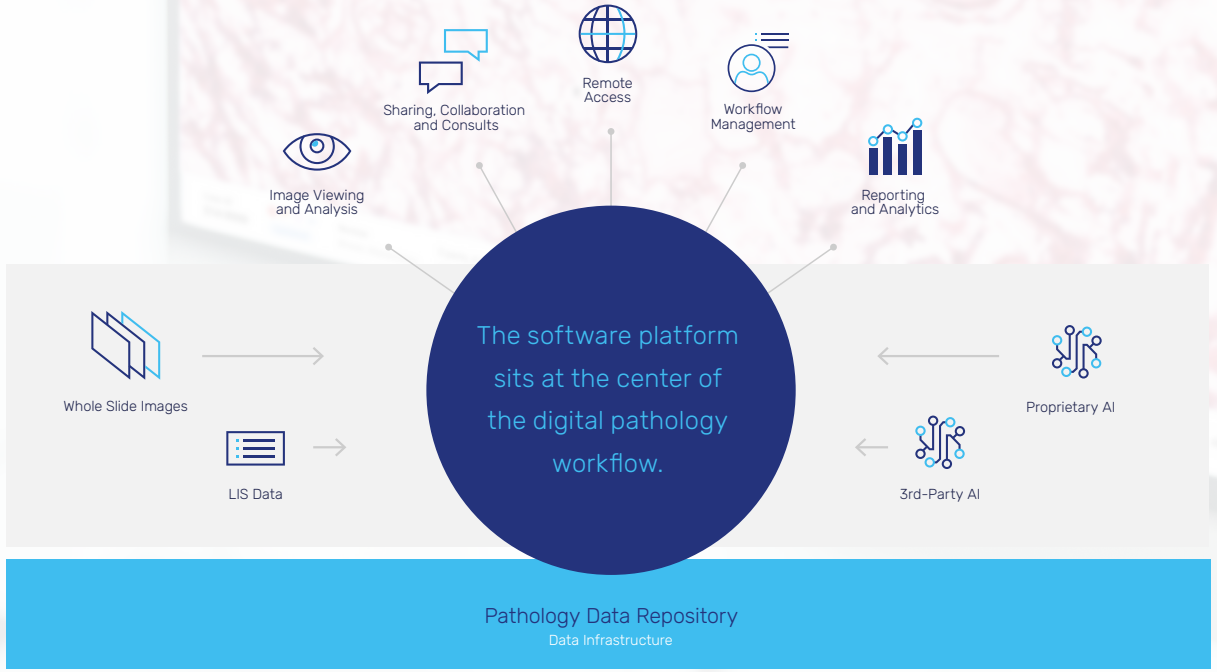
It will be the primary point of interaction for pathologists and serves as a connection point for the images coming from scanners, data from the LIS and analyses from any computational applications the lab adopts today or in the future. The success of any digital transformation hinges on choosing the right software solution, which is why evaluating software must be done first while it influences the choice of the upstream and downstream components of the digital pathology ecosystem.

The Value of a Software Platform

The right software platform solution goes far beyond an excellent image viewer and management experience. The software platform should have the flexibility to effectively integrate with legacy systems and new digital applications with minimal disruption. It should provide a seamless launching pad for current and future computational pathology applications (image analysis and AI applications) to help streamline operations and deliver new diagnostic insights.

The software platform must be pathologist-centered and easy to use. It is the tool that pathologists will use on a daily basis to perform case review and sign outs. It should:

- Help pathologists work more effectively by streamlining the multiple steps of the diagnostic processes, whether in the lab or remotely.
- Elevate the practice by enabling enhanced efficiencies, providing opportunities for improved quality of care, facilitating timely consults and interactive collaborations.
- Support a better work-life balance.
- Help attract and retain talent from the shrinking pool of pathologists with a properly designed digital environment.



Software plays a central role in the modern digital laboratory, connecting people, technology, data and information.

The following key points should be considered in the approach to the evaluation and selection process of the image management software platform.

System Openness & Interoperability

The general lack of technology standardization in pathology results in significant differences between various digital pathology solutions when it comes to how the software might interact with the rest of the lab's technology ecosystem. This can have an impact both on how well a software platform will fit into the current operations, and potentially limit what can be done with the technology in the future.

A software platform should:

- Integrate with the current or future LISs and provide robust support to enable target use cases.
- Support multiple image formats/scanners—including various brightfield and fluorescent images.
- Support image analysis tools and artificial intelligence (AI) applications into the digital pathology workflow and provide ease of expansion.
- Connect with the IT infrastructure supporting all of these components.

Scalability

Digital pathology becomes complex when it must expand to accommodate copious images, multiple locations, multiple users, new technologies and remote work. Ensure the software platform can support this type of scale to drive efficient workflows and that it can do so without sacrificing system performance/speed, affecting integrations, inhibiting workflows or creating burdensome workarounds.

With regard to scalability, the software should be evaluated to understand:

- Workflow configuration to power current and future laboratory needs, including multiple locations and multiple users within the network.
- Case volumes and forecasts for future expansion.
- IT infrastructure that can power the performance and volume requirements.

Computational Application Readiness

The system should also be AI-ready. Computational pathology is gaining momentum, and the potential of this technology in offering diagnostic and predictive insights is mostly untapped.

The software platform solution should:

- Integrate with AI applications from any source, not only from the chosen software platform company, but from multiple, third-party vendors, those developed by the organization and any combination of the above.
- Ensure that the AI is rendered natively within the software platform, to provide a unified workflow experience rather than depending on separate workflows.

The software platform adopted today will likely be what the team uses for years into the future. It must stand the test of time.

Pathologist-Centric Experience

Because of the critical role software plays in the routine use of digital pathology, usability is a significant factor in distinguishing between successful and unsuccessful digital implementations. The pathologists and lab team will be spending many hours a day in this software, performing core work in the chosen solution. The software platform should be purpose-built for pathologists and align with what pathologists care most about: the ability to deliver exceptional care in an organizationally efficient environment while supporting work-life balance, including the ability to deliver care in remote settings.

Important considerations from the pathologists' point of view include:

- A natural, intuitive, responsive and ergonomic image viewing experience
- Exceptional workload and case management efficiencies
- Seamless access to consult and collaboration pathways
- A rich set of annotation tools that assist with analysis and report construction
- Ease of participation in multidisciplinary team meetings

The digital transformation will affect all pathologists in the group. It is, therefore, advisable to engage and obtain input from multiple pathologists from diverse subspecialties and tenure at the time of software evaluation.

Security

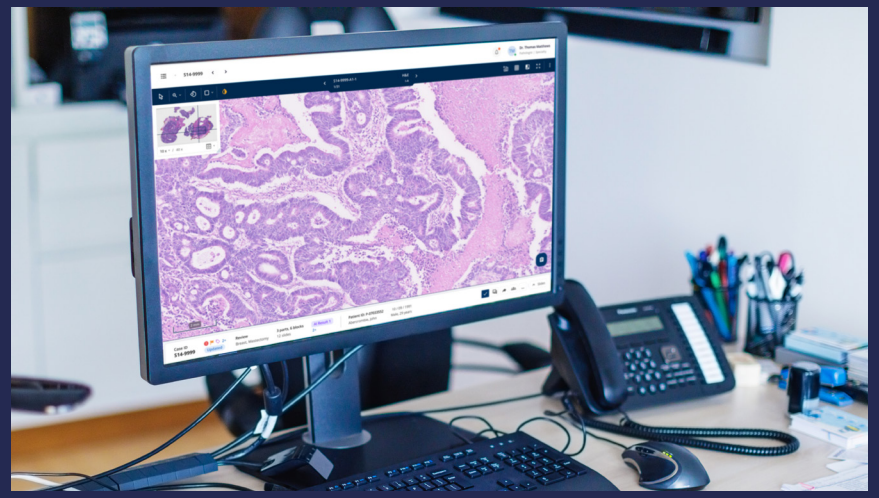
Ensuring data security is an important part of software selection. Choose a platform that provides:

- Comprehensive Data Encryption—The software should offer end-to-end encryption of data in transit (through TLS/ SSL), as well as encryption of data at rest (industry standard AES-256 encryption).
- Regulatory Compliance—The software should support compliance with HIPAA and GDPR regulations pertaining to data security.

Consult with the internal IT team to confirm advanced security features are in place to ensure the data is secure and private, accessible yet protected.

Selecting a Scanner

Scanner selection will represent a significant commitment and a substantial capital investment for laboratory operations, and must be considered with care.



Any digitization project requires the selection of whole slide imaging (WSI) scanners. The scanner purchase combined with storage solutions represents a substantial proportion of any new capital investment in the digital pathology implementation project.

It is important to be strategic in the selection approach as this decision will represent a significant commitment for laboratory operations and there are numerous considerations that play into the success of the project.

The following are key points to consider when approaching the scanner evaluation and selection process.

Determine the Number and Types of Scanners Needed

Understand use cases, workflows, operating hours and clinical service expectations to help clarify the number and types of scanners required to handle the digitization project. Gain consensus on the time of day all scans will be completed and ready for review by the pathologist. Consider prioritizing specimens depending on the clinical need and turnaround expectations. Some specimens will need to be prioritized for same-day evaluation while other low-priority cases may be scanned overnight.

Consider:

- Types of slides to be scanned (single, double, large format), types of imaging needed (brightfield, fluorescence, both) and other requirements such as Z-stacking for cytology specimens.
- Scanner capacity to handle typical slide volumes (daily, weekly, annual); allow for daily fluctuations.
- Scan time and throughput (time for images available for review).
- Rescan rates.

Image Quality

- Image quality is critical in the scanner selection process.
- Compare the scanned images to the histology material in your laboratory: evaluate stain quality, architectural, cytologic and nuclear details at various magnifications.
- Evaluate the scanner's ability to capture all tissue present on the slide.

Evaluate Laboratory Space

Evaluate the histology lab space requirements for the new instruments and consider placement that conforms with Lean principles for streamlined efficient operations.

- Review the specifications of each scanner as the footprint varies significantly. Consider:
  - Size and number of scanners the lab can facilitate
  - Weight and need for dedicated bench to assimilate vibration
  - Noise generated while in operation
- Account for additional space for the dedicated computer system and monitor(s) needed to run the scanner, as well as stations for the slides before and after the scanning has been completed. Plan for slide storage that facilitates re-scanning if needed.

Understand the Workflows

- Map the current and future workflows to match the proposed use cases.
- Prepare for a transition period and a progressive digitization rollout plan.
- Consider case assignment strategies that depend on image availability to accommodate for variable day-to-day workflow variations.

Establish Staffing Requirements

- Determine the human resources and operator expertise level required to support the scanner/s operations, including image quality control.
- Consider personnel and operational requirements for dual workflows (digital and analog), including an overlap time where continuation of case assembly, slide distribution/couriers will be required.
- Educate and provide training to histology personnel to ensure optimal quality of slide preparation required for scanning.

Choosing a Monitor

Monitors are frequently an afterthought when purchasing a system, but as pathologists will spend most of their time looking at the screen, this particular component is very important.

Technology selection focuses primarily on scanners and image management software given the long-term financial implications and operational commitment from the laboratory. While pathologists will rely on and interact with displays several hours each day, the role of the monitor—the last technical component of the pixel pathway—may often be overlooked.

Choosing a monitor that can render excellent diagnostic quality images is critical to ensuring a smooth and comfortable shift from microscope to digital workflows.

Monitors are ubiquitous. The technology around displays advances quickly, and there are numerous choices available in the market. Upgraded models are consistently released for consumers. When compared to the investment in scanners and software, monitor pricing presents a low investment risk per unit—but could amount to a significant expenditure when new monitors are deployed at scale for pathologists in the office and for remote use. Additionally, there may be opportunities to upgrade monitors over time to provide pathologists with more advanced features.

However, monitor selection for a digital pathology configuration must consider the many technical specifications and complex regulatory and laboratory accreditation requirements as these will ultimately influence the decision process.

Pathologists should become familiar with the display specifications of their daily diagnostic instrument, much as they would with their optical microscopes. The following summarizes the key points to consider in monitor selection for the pathologist workstation.

Monitor Types

There are three types of monitors, each varying in technical specifications and price availability on the market.

Consumer Off-the-Shelf (COTS)

As the name suggests, a COTS is what most people use as a primary computer monitor. It is the most affordable option.

Professional Grade (PG)

A higher-end consumer-grade display with superior optics, used by photographers and graphic professionals.

Medical Grade (MG)

MG monitors have standardized features to include higher resolution, contrast ratios, luminance and color stability to ensure a uniform experience. They can typically meet specifications longer and, as such, are the most expensive option.

Specifications of a Digital Display

The image management software vendor will likely provide minimum recommended specifications for the display, rather than requiring a specific model or brand. While there are no universal guidelines for the selection of monitors for use in digital pathology, attention should be paid to the monitor specifications to make sure the display meets the pathologists' performance requirements in a diagnostic environment.

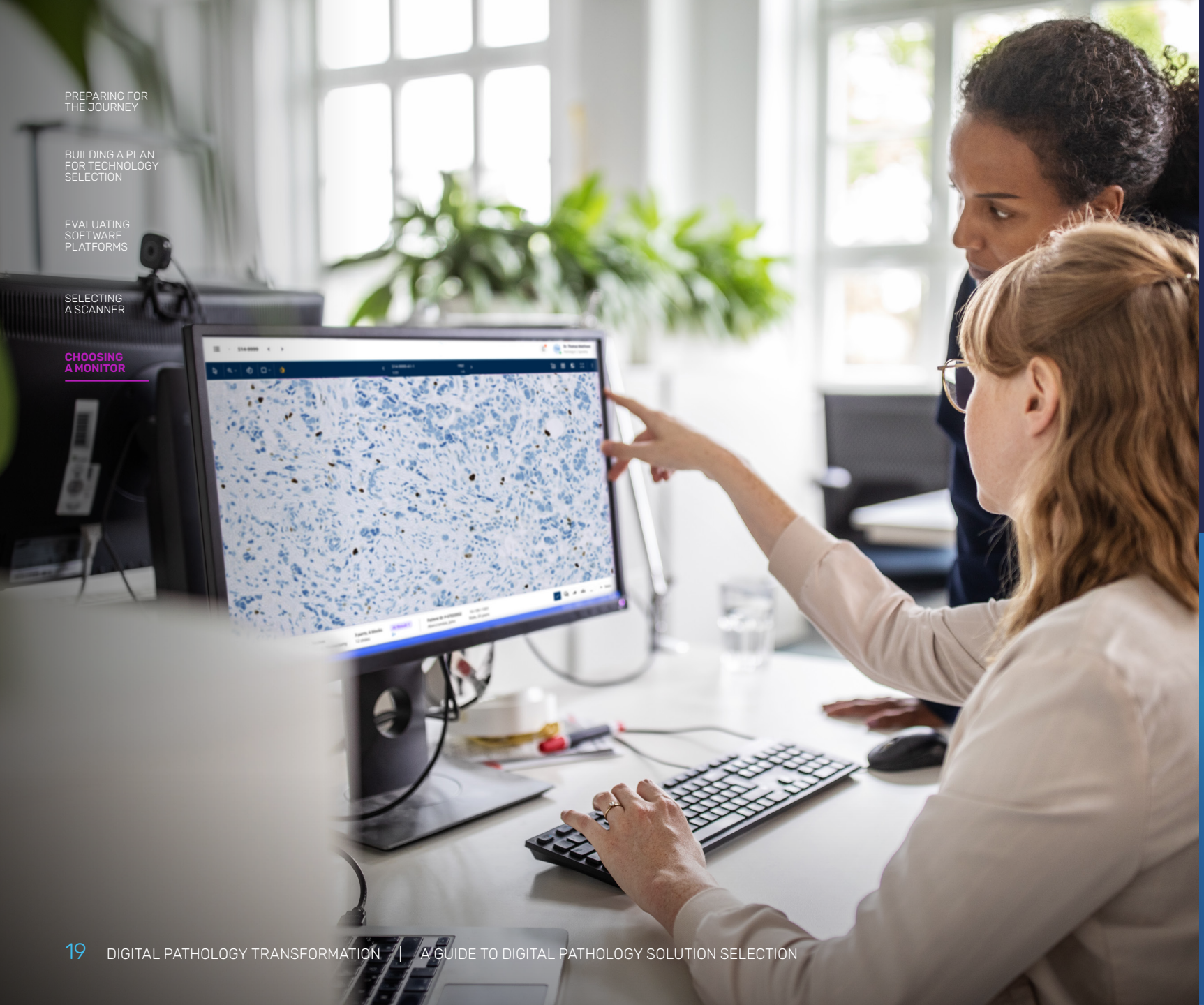
Here are some specifications to consider in the monitor selection process:

Display size	24" is considered a minimum recommendation; 27" screens are increasingly popular
Resolution	3 megapixel and above; but 4K or higher is recommended
Brightness	> = 350 cd/m2. Extra brightness may be required in a well-lit room or next to large windows. However, too much brightness may result in eye strain and fatigue.
Color	≥ 10-bit color depth and an extremely wide color gamut
Contrast ratio	1000:1 is suggested
Refresh rate	At least 60Hz—this is important to ensure smooth panning and zooming
Calibration	Self-calibrating sensors that automatically sense ambient lighting conditions of the workspace

Monitor Calibration and Quality Assurance

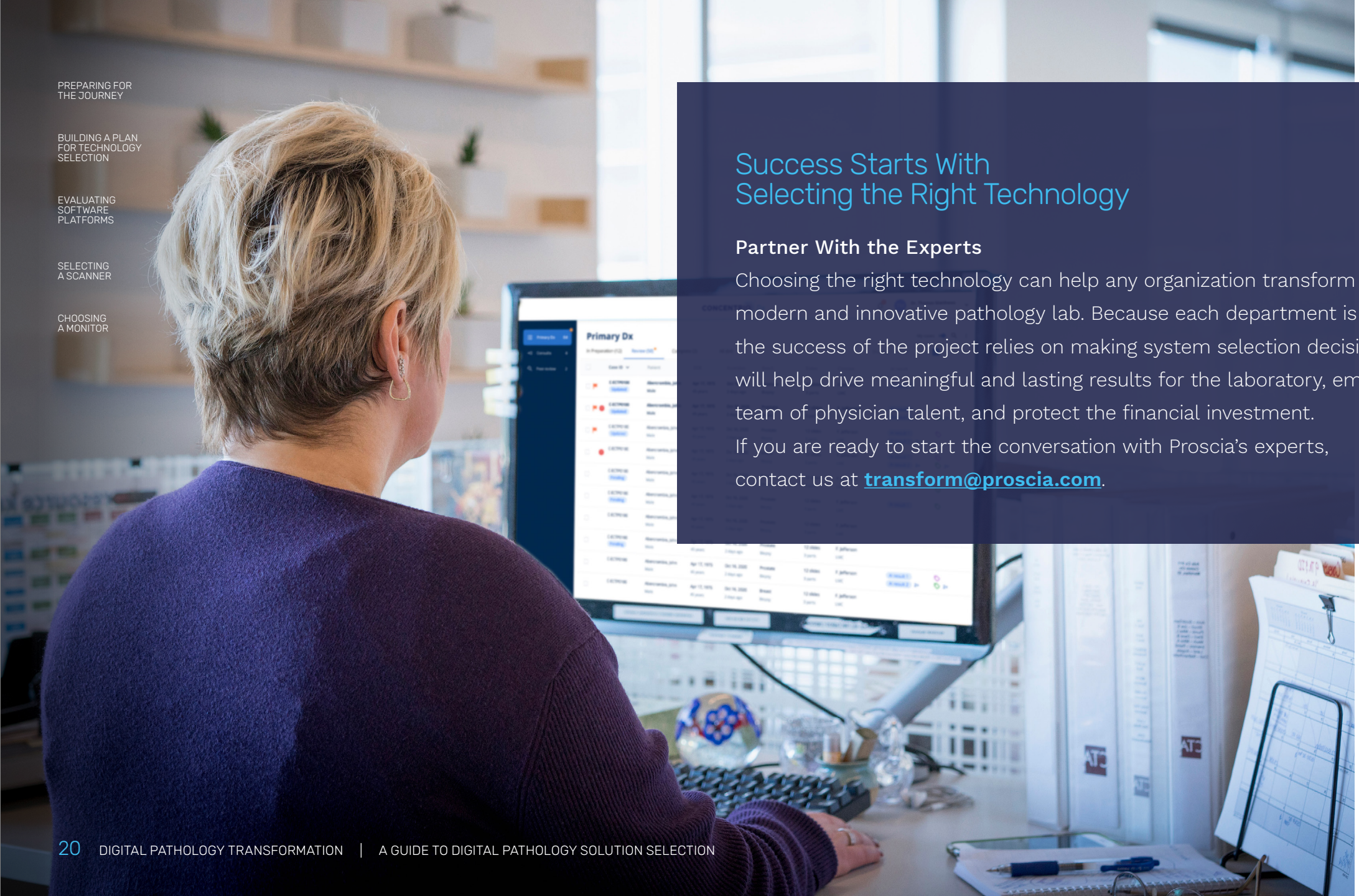
Calibration and quality assurance are important activities to ensure the monitor meets performance and specifications over time. Calibrate monitors against the same external standards aiming to obtain consistency between displays and to ensure that all the pathologists are exposed to the same image quality. This is particularly important if a pathologist is reviewing images across multiple monitors.

- Develop a calibration process. A calibration schedule may be recommended by a monitor manufacturer. Include the monitor QA schedules within instrument maintenance laboratory processes.
- Delegate the calibration and monitor maintenance activities to the appropriate professionals in your organization.
- Ensure calibration occurs when the reporting environment changes.



Putting it all Together

Monitor selection is complicated due to the many variables that need to be considered, including the numerous types of monitors available in the market, the variable display specifications, price and the regulatory environment where you practice. Getting display specification recommendations from the image management software company may be a good place to start. In the U.S., the regulatory conditions surrounding the 510(k) clearance of the monitor will undoubtedly influence the final decision, which in itself will impact the laboratory accreditation requirements and price.



Success Starts With Selecting the Right Technology

Partner With the Experts

Choosing the right technology can help any organization transform into a modern and innovative pathology lab. Because each department is unique, the success of the project relies on making system selection decisions that will help drive meaningful and lasting results for the laboratory, empower the team of physician talent, and protect the financial investment.

If you are ready to start the conversation with Proscia's experts, contact us at **transform@proscia.com**.

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