Nichols Management Group

KEY TRENDS WHITE PAPER SERIES | **JULY 2025**

Digital Pathology in 2025

Strategic Value, Future Potential, and Implementation Considerations

Introduction

Digital pathology (DP) has been in a (perhaps prolonged) transition from a promising innovation to a critical component of modern healthcare. Its adoption is accelerating in both private and academic institutions, driven primarily by advancements in artificial intelligence (AI), increasing demand for diagnostic services, and the need for operational efficiency. However, implementation is not an automatic "win" for every organization in 2025, as there are considerable obstacles and costs, and it is critical to know which problems you are hoping to solve so that your investment will yield an appropriate return. This report bypasses the hype that typifies reviews on this topic in hopes of providing valuable and pragmatic insight regarding DP's actual value both currently and in the future, along with strategic considerations for successful implementation, if/when you determine it is appropriate for your organization.

> "Today there are many more of the long-awaited applications that now make Digital Pathology much more feasible and desirable."

Brief History: The Promise of Digital Pathology and Reasons for the Lack of Expected Progress

In the early 2000's, Digital Pathology (DP) was expected to revolutionize the practice in a short time by offering enhanced workflows, easy consultations, AI diagnostics to improve quality, and even AI-rendered molecular surrogate testing based on morphology alone. The excitement around DP stemmed from the transformative impact that digitization had on the other major diagnostic specialty: Radiology. Digitizing film, as with photography, resulted in immediate benefits, even before the creation of software designed to enhance diagnosis: it replaced expensive film, eliminated development time and expense, and allowed for immediate distribution to radiologists wherever they were. Further, images were relatively small, monochrome, and 2 dimensional, making image file sizes relatively small and rendering images of high resolution fast.

Now let's consider pathology specimens. First, a paraffin tissue block is prepared from a processed and embedded patient sample, then a sectioned sliver of tissue is stained, labeled, and protected with a coverslip. After this process (which takes several hours), the slide is then physically organized (by patient and sample) and distributed to a pathologist for interpretation and reporting. Unlike radiology, with DP there is no process replacement (physical tissue blocks and slides still need to be created at stored). What's more, there is a new additional step of whole slide imaging, wherein the slide is converted to a color digital image, comprising dozens of smaller images tiled together. The costs of the scanners, tech time, and image storage/management are additional costs. These files are typically 2-3 GB, but can be as high as 40 GB, depending on the magnification used and the size of the specimen. Moreover, there are typically 2

to 5 slides per specimen and multiple specimens per patient encounter, making expected file sizes of 5 to 100GB per patient the norm.

The progress of DP has also been slowed by the reluctance of many pathologists to embrace a new technology. While some of this hesitancy is understandable, especially since they are now expected to view a 2D image of a 3D piece of tissue, which does pose some limitations on the ability to glean all the information from a specimen, most of the fear is unfounded, and pathologists adjust quite rapidly after some experience using the technology.

Another key reason for lack of adoption of DP is the historically limited number of use cases. Until recently, if pathologists were co-located with the lab and frequent consultations were not needed, it was difficult to calculate a return on investment, and there were only a few situations where there was a clear benefit to using the available digital diagnostic, prognostic and workflow algorithms, making the investment impractical for most practices. As such, implementation was confined to either academic centers funded by research grants or large labs that were geographically dispersed desiring to consolidate tissue processing and special testing.

However, today there are many more of the long-awaited applications that now make DP much more feasible and desirable. The following will review these along with practical considerations.

Current Value of Digital Pathology

Positive Clinical Impact

Case Turn-Around Time: Depending on your physical infrastructure and workflow, DP may allow for significant savings in turn-around time, especially when pathologists are not all co-located with the laboratories. If all slides are to be digitized, tissue block and slide order need not be reconstituted several times in the lab process (especially with non-sequential case storage), allowing for true first-in/first-out (FIFO) workflow with significant time saving in the lab. Newer workflow software also offers diagnostic previewing, prioritization by likely clinical severity, automated special stain ordering and even preliminary report generation, resulting in better TAT, especially for the most clinically significant cases.

Diagnostic Improvement: Algorithms are now able to evaluate much more than what has been a long-term limitation to only prostate, breast, and lymph node cancer detection, including not only more tissue types but also subclassifying and grading. Further, many non-cancer diagnoses are becoming available, for example inflammatory diseases of skin and the gastrointestinal tract. These new algorithms will likely significantly reduce the likelihood of error and help ensure comprehensive and consistent reporting.

Consultations: While pathologists use subspecialist experts both within and outside their institutions, the process of obtaining one is prolonged and logistically difficult with

traditional pathology, requiring paperwork, slide shipping, and risk of lost/broken slides. As such, only the most problematic cases typically get sent for second opinions. However, using DP enables immediate access to internal colleagues as well as a marketplace of outside consultants, lowering the physical and psychologic obstacles to seeking expert advice.

Case Retrieval: While perhaps not the most impactful aspect of DP, glass slides are often stored offsite, making review of prior tissue slow at best, and sometimes slides are misfiled, making them impossible to retrieve without recutting the paraffin tissue block that may not include the diagnostic areas of interest.

Cost Savings

Implementing DP can lead to significant cost reductions depending on a laboratory's infrastructure. By digitizing slides, institutions can save on physical storage and retrieval, slide transportation, and labor. All of the items mentioned above that improve turnaround time (including a FIFO workflow, lack of requirement to keep cases sorted throughout the various steps in the lab, filing sequentially, etc.) will also save labor costs by improving both efficiency and productivity. Moreover, AI integration can increase productivity via algorithms that not only prescreen but also categorize, grade, and highlight key areas of interest with preliminary report generation, improving the productivity of the most expensive resource: the pathologist, without lowering (and likely improving) quality.

Increased Revenue

DP potentially enables laboratories to handle higher case volumes without proportionally increasing staff, thus allowing for more revenue in existing space as well as the ability to develop outreach programs in the community. The scalability of digital systems also allows institutions to expand service volume and case type via access to pathologists who can access cases remotely without having to relocate. This flexibility is especially helpful when only a part-time pathologist is needed and when certain expertise is infrequently needed but critical, e.g., non-neoplastic kidney, liver, ocular, or brain biopsies.

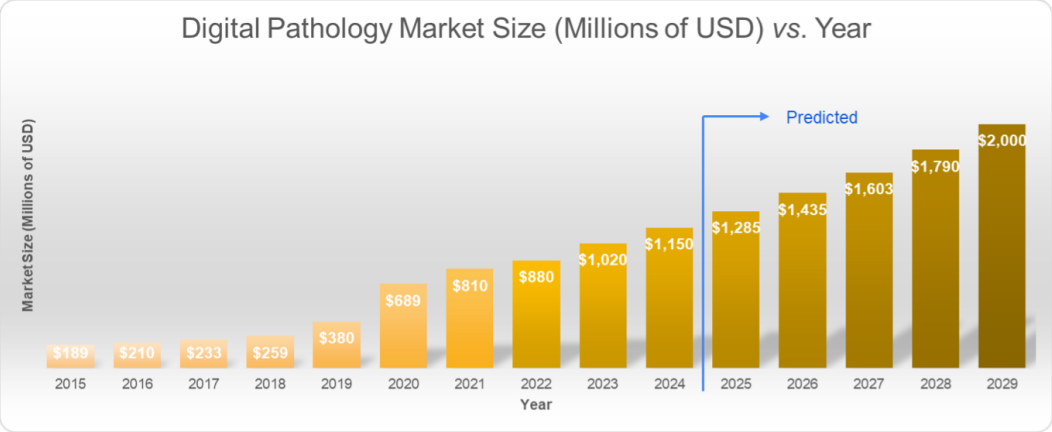
Talent Recruitment

Digital pathology systems appeal to a tech-savvy workforce. Institutions adopting DP are better positioned to attract and retain talent, offering flexible work environments, which are increasingly valued by professionals. Pathology, like many medical specialties, is facing a serious capacity crisis, and institutions with digital workflows offer younger doctors both workday and workplace flexibility, along with greater opportunity for collaboration, which are key factors for both recruitment and retention. Lab personnel also desire to be associated with institutions that are offering state-of-the-are technology.

Limitations

Note, however, that there are significant limitations to current AI integrations. First, the process of accessing the AI software within the pathologist workflow can be clumsy and time-consuming, depending on the setup. Also, these savings are dependent on tissue type. For example, a dermatopathologist is unlikely to be faster with AI than without, since low-magnification pattern recognition is the key to diagnosing the majority of cases and occurs in seconds. Further, AI advancements remain limited to small range of tissue types and diagnostic categories, but this range is expanding, especially in the last few years. Another key caveat to note is that when AI identifies an area of interest, the pathologist must evaluate it, and if an algorithm produces many false-positive findings, it may actually slow the pathologist down without adding much value.

Future Value of Digital Pathology



Digitization of pathology samples via whole slide imaging is the foundational step in preparing for future advances in AI for workflow, diagnostics, prognostics, and theranostics. None of these upcoming and exciting advances are possible with traditional glass slides. Those institutions who are early adopters will be best positioned for long-term competitiveness. Since there are significant technical, logistical, and even emotional hurdles that need to be cleared before DP can become the mainstay protocol for a pathology laboratory, there is risk in waiting to at least begin the transition. Therefore, finding at least limited ways to integrate DP into your practice will facilitate more comprehensive adaptations when appropriate.

Improvements of Current Capabilities

In addition to encompassing more and more tissue types and diagnostic categories, DP software will become more seamlessly integrated with existing laboratory information systems (LIS), saving time and effort, while increasing utility, cost-savings, and quality. Software currently exists that allows the pathologist to view and scan various separate stains of the same tissue in a split view, so that the exact same microscopic foci can be

evaluated simultaneously. Increasingly, virtual special stains will supplant some chemical and immunologic ones, saving time and cost.

Finally, Quality Assurance for Surgical Pathology and Cytology is a tedious process requiring significant manpower and time when performed correctly. Cases must be selected, retrieved, distributed, cataloged, analyzed, summarized, and then refiled. Digital pathology can handle almost all of these functions automatically, except for the second pathologist review, which ultimately could be limited to only significant discrepancies. Such a process would facilitate a more thorough and effective QA program and, by extension, improve the quality of care.

Expanded Role of Pathology

AI has been increasingly shown to be able to identify histologic correlates (on routine glass slides) of known genetic mutations that cannot be readily discerned by a human eye. These findings may obviate the need for expensive molecular testing in certain cases. Morphologic features identified by AI may also provide prognostic information and even predict therapeutic response to various pharmacologic agents, helping expand the capabilities and value of histology while saving expense and time. These are perhaps the most exciting prospects for DP.

Global Health Improvement

There is a serious global shortage of pathologists. AI-generated diagnostics may allow for many simple cases to bypass pathologist review altogether, which may be a preferable solution to existing manpower deficits and crippling delays in certain regions.

Pitfalls and Challenges

Underestimating Infrastructure and Personnel Needs

Transitioning to DP requires a significant investment in IT infrastructure, including high-resolution scanners, secure image and data storage solutions, and robust network capabilities, along with the additional physical space required to accommodate these. Additionally, lab personnel to scan slides and maintain instrumentation must be accounted for.

Resistance to Change

Efforts to adopt DP will face resistance from some pathology and lab staff who are accustomed to traditional workflows, the percentage of which will depend on the organization. These individuals may not only resist but try to subtly "sabotage" progress and success. Fortunately, there is increasing recognition of the inevitability of the transition to DP, lowering the resolve of those opposed. Early alignment of key stakeholders in the lab as well as IT, clinical practices and administration is therefore critical. Change management strategies and education on the benefits both to the lab

and patient care are essential to facilitate a smooth transition and help improve user buy-in.

Integration with Existing Information Systems

Ensuring compatibility between DP systems and existing laboratory information systems (LIS) can be challenging. Further, even when a laboratory is prepared to make a change, incompatibility with an institutional EMR may prevent progress. Without complete interoperability, many of the workflow efficiencies will likely not be realized. Finally, selecting DP software vendors with proprietary ecosystems can limit both scalability and integration with future AI tools that may become standard-of-care, so be sure to consider open systems from companies likely to have longevity in this competitive market.

Overcommitment

It may be tempting to make a wholesale transition all at once; however, the likelihood of failure at several points is dramatically increased with such an approach. It is safer to start with a limited operation (perhaps with a single clinician, scanning one type of tissue only, and just 1-2 pathologists). Once the workflow has been optimized and quality confirmed, expand incrementally to include more clinicians, tissue types and pathologists, scaling at a rate that is commensurate with your experiences. Use performance data to evaluate successes and workflow improvements in order build organizational confidence that will facilitate adoption and further investment.

Conclusion

Digital pathology has the capacity to revolutionize diagnostic medicine, by increasingly providing substantial benefits in operational efficiency and, over time, clinical outcomes. By understanding its current capabilities and limitations as well as its future promise, an organization can make pragmatic decisions and how and when to implement DP, while avoiding common pitfalls. Digital pathology is not only an emerging trend; it is becoming an organizational imperative as a prerequisite for AI-driven laboratory medicine, and institutions who are not at least actively evaluating how a transition might be feasible will likely find themselves critically behind.

NMG is aware that investing in digital pathology is an important decision for a health system. If you would like assistance in evaluating the benefits and risks to your organization, or are already prepared to invest, NMG has over 20 years of experience in ensuring efficient and compliant implementations.

Author: Richard Lash MD brings over 25+ years of laboratory medicine expertise in the realms of academic, clinical medicine and business to his role as Senior Consultant at NMG. He earned his BS, Summa Cum Laude, Phi Beta Kappa and his MD (with Alpha Omega Alpha honors) at the University of Michigan.

He trained at the Cleveland Clinic where he was Chief Resident with fellowship training in Gastrointestinal pathology. He later established a unique medical practice noted for its peerless quality and sophistication in his role as Chief Medical Officer & Executive Vice President of Operations of a national anatomic and molecular pathology company serving over 1.2 million patients/year.

He currently is a Clinical Professor of Pathology at UT Southwestern Medical Center, having published 88 publications in major medical journals, including 6 book chapters, which have been cited over 3000 times.

VISIT: NICHOLSMANAGEMENTGROUP.COM

EMAIL: INFO@NICHOLSMANAGEMENTGROUP.COM

CALL: 207.363.8230

The Nichols Management Group, Ltd. (NMG) is the medical laboratory industry leader in strategic development, mergers, acquisitions, joint ventures and operations management services. NMG provides laboratory consulting services focused on lowering costs, increasing revenue and optimizing laboratory operations with experts in:

- Advisory
- Financial
- Information Technology
- Scientific
- Operational
- Technical
- Marketing
- Strategic
- Interim Management
- Quality
- Recruitment
- Business Development

NMG has been the driving force behind many of the most successful ventures in laboratory management for over 35 years.