WhitePaper

Anatomic Pathology At the Tipping Point?

The Economic Case for Adopting Digital Technology and AI Applications Now

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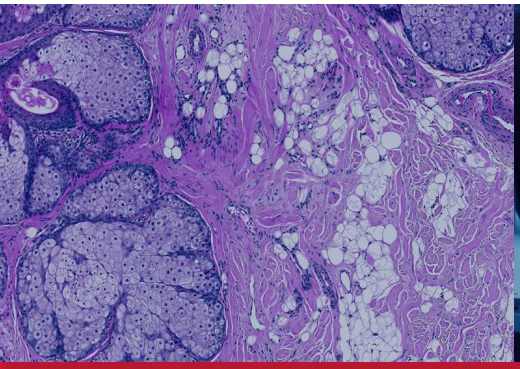

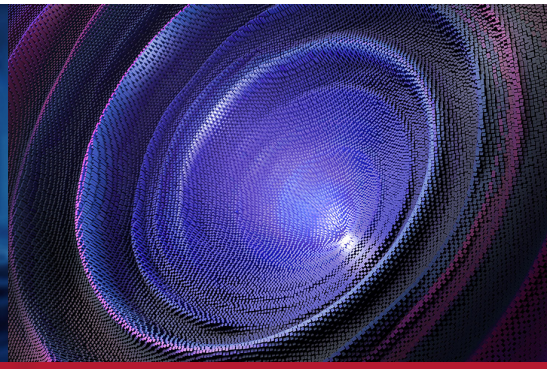

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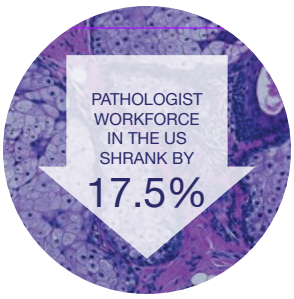
BETWEEN 2007–2017



The traditional pathology business model is transforming at a steady pace. Between 2007 and 2017, the pathologist workforce in the US shrank by 17.5%, while the pathologist's diagnostic workload rose by 41.7%.[1] Furthermore, reimbursement for pathology services continues to decline, with Anthem currently implementing cuts to anatomic pathology CPT codes, ranging from 50% to 70% of 2018 Medicare fees.[2]

Labs are struggling to remain profitable as they grapple with these challenges, which have built at an alarming rate over the past decade, according to ongoing coverage in *The Dark Report*. Moreover, the manual and subjective microscope-based practice of pathology leaves significant efficiency and accuracy gaps, resulting in a lack of concordance among pathologists and a heightened risk of misdiagnosis for patients.

"Never before has the pathology profession experienced such a confluence of factors that collectively puts pressure on the private practice model that has dominated for decades, while being faced with steadily eroding reimbursement for pathology services," said Robert L. Michel, Editor-in-Chief of *The Dark Report* and its sister publication, *DARK Daily*.

"Pathology's classic economic business model and the rapid changes in diagnostic technologies and genetic medicine mean that many pathology laboratories operate on such a thin margin that it may only take one more severe adverse event to put the most financially stressed labs out of business," according to Michel. "Healthcare's ongoing transformation is another powerful reason to expect that disruption to pathology's long-standing business and clinical practices will continue."

One wide-ranging solution that's been proposed to address these systemic challenges is digital pathology (DP).

Until recently, however, digital pathology adoption has been limited by a lack of regulatory approval, insufficient return on investment, and the inability of technology to support complete transformation, like the storage needs created by whole slide images averaging one gigabyte each in size.

Just as the digital transformation of adjacent specialties such as radiology has shifted the economic and practical outlooks of professionals in those spaces, the same is happening today as a result of the implementation of next-generation digital pathology systems.

Through the adoption of digital pathology, glass slides are digitized using a whole slide image scanner, then analyzed through image viewing software. Although the basic viewing functionality is not drastically different than that provided by a microscope, digitization has brought about improvements in lab efficiency, diagnostic accuracy, image management, workflows, and revenue enhancements.

As implementation of digital pathology increases, the urgency to do so also amplifies.

"Digital pathology has become a necessity," said Dr. Marilyn Bui, a board-certified practicing pathologist, President of Medical Staff at Moffitt Cancer Center, and immediate past President of the Digital Pathology Association. "Recent technological advancements like the shift from desktop to high-throughput whole slide image scanners and regulatory wins like digital pathology systems receiving FDA clearance have paved the way for the wide-scale adoption of digital pathology for labs both large and small."

While the value of adopting digital pathology into routine workflows has been substantiated by more real-world examples of practical implementation, this field of technological innovation has recently undergone further transformation as AI-based computational applications have emerged as an integral part of the digital pathology workflow in some settings.

These computational applications add information in advance of or after pathologist review of cases, augmenting the pathologist's capacity to make informed decisions and streamlining the process by which cases are received and signed out.

While keeping the pathologist in the driver's seat, the AI runs in the background, enabling the pathologist to practice at the top of their license. Though AI as applied to pathology is a more recent development, it is already creating new opportunities for the clinical practice and business operation of anatomic pathology.

What follows is a synopsis of recent research and real-world cases which prove the economic necessity of adopting digital pathology platforms and AI applications now. We'll hear from a handful of digital pathology pioneers who have demonstrated the success of new business models, analyze how AI applications are already transforming cancer diagnostics, and look to the future of personalized medicine made possible by the adoption of digital pathology.

Chapter 1:

Digital Pathology Pioneers Prove Its Success and Long-Term Viability

Over the past decade, many pioneers have proved the benefits of digital pathology in practice. One of them is Zoltan Laszik, MD, PhD, Professor of Clinical Pathology at the University of California San Francisco (UCSF) School of Medicine, who saw the promise of digital pathology early on and pushed for the investment.

What began as a desire to decrease the time it took to share and diagnose frozen sections among UCSF's three hospitals has resulted in a totally new approach and digitally enhanced workflow. "We started off by demonstrating the initial equivalence between digital and glass reads and found that there were no delays outside of those related to human error," Laszik told *The Dark Report*. "We could see the advantages and efficiency very quickly."

Laszik said this evaluation was so successful that UCSF implemented the digital pathology system in February 2015, starting with frozen sections and moving to the broader volume of pathology slides.

"We conducted a very large internal validation with 30 pathologists and 800 slides and turned it into an even larger study than what Philips did for FDA approval," he said. "It was a success story; there was not a single case that was misdiagnosed because of the digital technology, and the benefits were immediate from hospital to hospital."

Today, Laszik and UCSF are approaching a 100% digital pathology operation, having serialized the adoption by specialty. As a top-tier academic medical center, UCSF may be setting the bar for digital adoption in the US.

Further examples of productivity enhancements and operational improvements can be gleaned from recent articles in the *Archives of Pathology and Laboratory Medicine.*

The article "Complete Digital Pathology for Routine Histopathology Diagnosis in a Multicenter Hospital Network"[3] cites a study from Granada University Hospitals (GUH) in southern Spain. GUH reported the results of a rapid six-month transition from analog to digital pathology for primary diagnosis:

RESULTS

- 21% more cases signed out by pathologists per year on average since full implementation in September 2016.
- Some of the analog workflows were rendered redundant, leading to better laboratory efficiency in the preanalytical phase. Work of three full-time histotechnicians moved to .5 full-time employees, with laboratory staff traditionally in charge of tasks dedicated to other duties.
- 28% change in amount of relative value units (RVU), from 57,314 RVU per pathologist in 2015 to 73,350 in 2018.

Another example explained results at Memorial Sloan Kettering Cancer Center (MSK), a high-volume, academic cancer and research institution in New York City. In "Implementation of Digital Pathology Offers Clinical and Operational Increase in Efficiency and Cost Savings,"[4] also published in the *Archives of Pathology and Laboratory Medicine,* MSK reported the results of implementing digital pathology and whole slide imaging (WSI) in breast, gastrointestinal, and genitourinary pathology services:

RESULTS

- Decreased slide requests from the department slide library resulted in redistribution of three full-time employees from the slide file room and incorporated into the DP operations workflow.
- Pathologists ordered fewer ancillary studies by up to 75.4% when WSIs were available. Immunohistochemistry orders

decreased by 30% in cases with documented review of prior patient WSIs.

- Time and motion study showed an overall 13.4% (43 minutes, 9 seconds) time savings in the pathologist's workday as a result of digital pathology.

Nicolas G. Cacciabeve, MD, Managing Member at Advanced Pathology Associates (APA) in Rockville, Md., stands out as another digital pathology pioneer. Cacciabeve's practice serves a wide geography of hospitals across Virginia and Maryland, and as a result of the advancements in digital pathology, APA has become a "distributed pathology practice." Each of APA's subspecialty pathologists has a primary hospital location. "We place a lot of value in consulting, case sharing, and communicating in our practice so that each hospital receives the benefit of our combined knowledge and experience.

"Adding whole slide imaging to our practice workflow has led to an improvement in the way we do things," said Cacciabeve. "It drives efficiency and improves access to expertise. The older model of community hospitals relying on the expertise of one, two, or three in-house pathologists is being supplanted through the use of digitization. With digitization, I can send a whole slide image to any subspecialty pathologist in our practice or to any expert anywhere within minutes."

As a part of APA's adoption of whole slide imaging, Cacciabeve implemented Proscia's Concentriq digital pathology platform. He and his team use the software to manage whole slide images across geographies, connecting pathologists with the images and data they need to perform their jobs, even at remote sites.

By improving access to expertise and facilitating collaboration, Cacciabeve sees digital pathology also increasing the speed and accuracy of diagnosis while reshaping the standard of care.

"Digital pathology can take a significant amount of the time for diagnosis out of the system, and that has time implications for the patients' treatment and discharge," Cacciabeve explained. "Because of this, the standard of care is quickly going to evolve away from the analog days of looking at slides and sharing glass among ourselves to the digital age where we share images. As standards are set, pathologists are going to have to quickly adapt or be left behind.

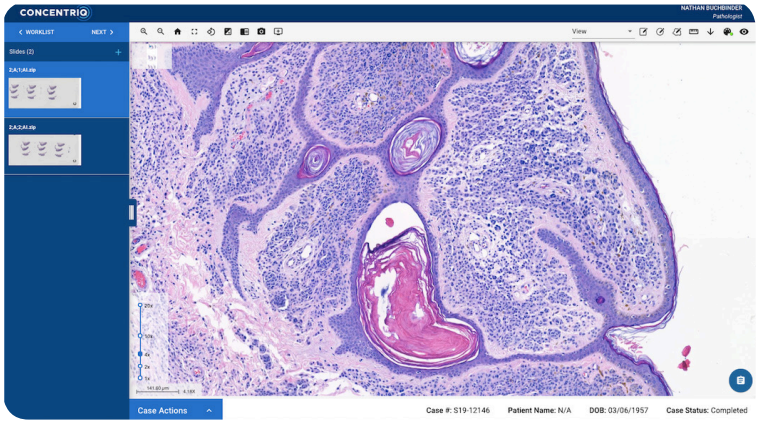
"The digitization of slides is a precursor to the next and greater disruption that's occurring," he continued, "because now that we have digital images, AI software can overlay the digital image and make usable predictions of what's on that slide, and oftentimes as useful, to predict what is not on the slide, to assist the pathologist.

"When we talk about diagnostic consistency and quality, AI-assisted diagnoses will demonstrate improved performance," Cacciabeve added. "Because of this, the standard of care is quickly going to evolve away from the AI-unassisted analog days of looking at slides to the AI-assisted digital age where we share images screened by AI. Similar to the change from thick smear PAP smears to computer-assisted ThinPrep vaginal cytology, as standards are set, pathologists are going to have to adapt or be left behind.

"When we talk about efficiency and financial savings, again, AI is going to have a tremendous impact on pathology practice and its business model while empowering pathologists to spend more time on those cases, digital slides, or areas of digital slides that require the most attention."

Together, digital pathology and AI are giving anatomic pathology laboratories new tools to handle the growing workload of cancer diagnostics.

Concentriq, shown below, enables image-based workflow management and serves as a launchpad for AI applications.



Chapter 2:

How AI Applications Are Revolutionizing Cancer Diagnostics and Research Today

With today's increased demand for biopsies comes the greater need for specialization. While the benefits of digitization are already paying dividends for pathology laboratories of all sizes, examples of diagnostic decision support, productivity enhancements, operational efficiency, and cost savings will increase with wider adoption of computational solutions, including AI applications.

The field of computational pathology has moved beyond academic research, with commercial products in use at both academic and commercial laboratories in the US and abroad. These applications are generally subspecialty-specific, focused on driving efficiency and quality in routine pathology work, to augment the pathologist's diagnostic prowess and improve outcomes while saving time.

Kiran Motaparthi, MD, is already realizing the benefits of AI at the University of Florida (UF) College of Medicine, where he is Director of Dermatopathology and Associate Professor in the Department of Dermatology.

"We are exploring the AI-assisted review of whole slide images of skin biopsies by DermAI as we continue to measure the potential impact of AI on dermatopathology," Motaparthi said. "The application provides automatic prioritization and assignment of high-impact cases."

Motaparthi says that routine caseloads in dermatopathology may benefit from computational evaluation and validation. "Applying DermAI to workflows can potentially increase diagnostic efficiency," he said. "Eighty percent of our time is spent on less than 20% of

identifiable caseload. So, anything that can improve workflow and efficiency has the capability to help us focus more on challenging and impactful cases.

"This tool makes the leap to aid in triage," Motaparthi continued. "It doesn't get tired, it doesn't get distracted, it doesn't miss one piece of tissue on a slide. So this could be very exciting, very revolutionary."

Motaparthi noted that the technology can be extended to many areas of pathology.

As further evidence of the advancement of clinical-grade AI development, companies such as Paige, Lunit, and others have made announcements about their own subspecialty-specific, AI-enabled digital pathology products in the past year. Commercial agreements have been announced by companies such as Royal Philips and Paige; IBEX with UPMC (prostate cancer diagnostics); and Nucleai and Protean BioDiagnostics (gastrointestinal, breast, and prostate tissue analysis, other indications).[5-7]

Additionally, large American medical centers are developing partnerships to build new subspecialty-specific AI applications and improve the accuracy of existing solutions. In December 2019, Proscia announced a partnership with Johns Hopkins School of Medicine[8] to bring novel AI applications to several high-impact diseases. This added to the company's existing partnerships with organizations such as the University of Florida, Thomas Jefferson University Hospital, and others that had been initially focused on dermatopathology.

Labs that have already adopted digital pathology are well positioned to expand their implementations with AI applications.

Pathology laboratories that have already adopted digital pathology, such as Cacciabeve's Advanced Pathology Associates, are well positioned to expand their implementations with these AI applications.

"We are already seeing the deployment of AI in labs, and we know how important it is for our practice to stay ahead of the curve," Cacciabeve said. "Soon there will come a time when pathologists won't even think of looking at a case without it being screened by AI."

Chapter 3:

Digital Pathology and AI in Practice: What's Next?

At Protean BioDiagnostics, every slide is digitized. The laboratory employs a new business model centered around using digital pathology and AI applications to improve access to pathology services and precision oncology, as well as reduce time to diagnosis.

Anthony Magliocco, MD, former Chair of Anatomic Pathology and Executive Director of Esoteric Laboratory Services at the Moffitt Cancer Center, is the President and CEO of Protean BioDiagnostics in Orlando, Florida.

"At Protean, we recognize that every cancer patient is unique and requires individualized treatment. We use the very latest technologies available to combine routine pathology services, precision oncology, second opinions, liquid biopsy, genetics, and genomics all in one lab. From there, we provide these services for patients at cancer centers of any size, anywhere in the world," Magliocco told *The Dark Report*.

"We actively deploy AI on top of our digital pathology system to increase efficiency, run more cases, make fewer errors, and, as a result, generate more revenue."
—Anthony Magliocco, MD

The future is about data, Magliocco says, and 70% or more of healthcare data comes from pathology. Therefore, the future of medicine doesn't happen without putting the right pathology data management infrastructure into place.

For Protean, this initially meant the adoption of a digital pathology platform. Magliocco cites advantages such as "intelligently" managing whole slide image data, alongside the other clinical information, as a part of delivering on the laboratory's personalized approach to cancer diagnosis.

"We started using the platform as a center point to manage all the kinds of diagnostic data we collect in one place," Magliocco said.

"Now, with all the data centralized, we can apply AI applications on top of our advanced diagnostic tools to ensure better diagnostic evaluation for every patient.

"We actively deploy AI on top of our digital pathology system to increase efficiency, run more cases, make fewer errors, and, as a result, generate more revenue," he continued.

Magliocco's vision for the future of diagnostics and care goes even further.

"One day all physicians should be able to look at a dashboard and see the full patient, so they can make better decisions about treatment, and about wellness and keeping patients well," Magliocco said. "That's what we're building at Protean with digital pathology as the foundation."

Conclusion

The unprecedented confluence of economic and scientific factors facing traditional pathology is daunting, but recent technological advancements and demonstrated success stories show that digital pathology's future is bright.

The impact of digitally—and computationally—augmented laboratories is already being realized. "Digital pathology and artificial intelligence expand the abilities of the pathologist, helping to fill gaps in care while also helping doctors make diagnoses in areas that are underserved by pathology today," said Magliocco.

All anatomic pathology groups in the US must confront the new reality: The era of primary diagnosis using whole slide images has begun. With many pathologists now agreeing that the field needs to move beyond the microscope and embrace the overall diagnostics, the next step for many is convincing pathology groups and pathology labs to make the investment.

"Gaining knowledge and first-hand experience with digital pathology is vital to the future success of your lab. If you're even remotely considering digitization, the time is now."
—Mike Bonham, MD

Mike Bonham, MD, is the former Head of Pathology at Driver, a California-based medical services startup that adopted digital pathology across its organization. Now Proscia's Chief Medical Officer, Bonham is familiar with how moving to adopt digital pathology may challenge the status quo.

"It starts with education," Bonham said. "Set up meetings with pathology laboratory vendors to learn what's out there. Educate executive leadership and lab managers on what you find out about the solutions and the clear, immediate, and far-reaching benefits and return on investment of adopting a digital pathology platform."

Moving forward, capitalizing on current trends, improving on existing implementations, and continuing to adopt AI are critical to ensuring that pathology—and pathologists—remain the essential part of diagnostic medicine they always have been.

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Featured Contributors

Marilyn M. Bui, MD, PhD, is a Senior Member in the Department of Pathology at Moffitt Cancer Center, where she serves as the Scientific Director of Analytic Microscopy Core, the Section Head of Bone and Soft Tissue Pathology, and the President of Medical Staff. Bui served as President of the Digital Pathology Association in 2019 and is a Professor and Director of the Cytopathology Fellowship at the University of South Florida (USF) Morsani College of Medicine. Bui's expertise includes bone and soft tissue pathology, cytopathology, biomarker testing, and digital pathology. She has published over 180 peer-reviewed articles, 21 book chapters, three books, and serves on committees organizing national meetings on pathology education. She has frequently lectured both nationally and internationally, including keynotes. Bui chaired the Expert Panel of Quantitative Image Analysis (QIA) project working on a guideline to improve accuracy, precision, and reproducibility of breast cancer HER2 IHC QIA interpretation and reporting of the College of American Pathologists (CAP).

Anthony M. Magliocco, MD, FRCPC, FCAP, is President and CEO of Protean BioDiagnostics and Professor of Pathology and Oncology. Magliocco is an internationally recognized cancer expert with over 30 years of experience in creating and deploying advanced diagnostics to help cancer patients. He is board certified in pathology and has held multiple leadership positions in Canada and the US, including Professor and Chair of Pathology at Moffitt Cancer Center and Executive Director of Esoteric Laboratory Services at Moffitt between 2011 and 2019. He also served as Scientific Director of Moffitt's internationally renowned tissue bank between 2011 and 2019. He has founded new fellowships in molecular diagnostics and digital image analysis, and directed the CAP CLIA implementation of the Moffitt STAR™ NGS assay. His other roles included chairing the pathology committee of RTOG oncology, serving on the NCI GU clinical trials steering committee, and also directing the Canadian Breast Cancer Foundation tumor bank in Calgary, Canada. Magliocco has published over 200 manuscripts with more than 10,000 citations.

Featured Contributors

Zoltan Laszik, MD, PhD, is the Director of Digital Pathology and Renal Pathology at the University of California San Francisco. He has published extensively on various aspects of native and transplant kidney diseases. His laboratory is developing novel tissue-based interrogation technologies, including high dimensional multiplexing immunofluorescence microscopy to study inflammation, organ rejection, and cancer. He is leading the efforts at UCSF for the adoption of digital and computational pathology for primary diagnosis.

Kiran Motaparthi, MD, serves as Associate Professor, Residency Program Director, and Director of Dermatopathology in the Department of Dermatology at the University of Florida College of Medicine. He earned his undergraduate degree from Johns Hopkins University and his medical degree from Baylor College of Medicine, and completed residency in dermatology at Baylor College of Medicine and fellowship in dermatopathology at the University of Texas Southwestern Medical Center. Motaparthi has authored 70 publications and serves on the editorial board of *Dermatology World Insights & Inquiries*. His interests in pathology include inflammatory dermatopathology and artificial intelligence.

Nicolas G. Cacciabeve, MD, FCAP, ACPE, is a board-certified pathologist who holds the positions of Medical Director of Laboratory Services and Chairman, Department of Pathology at White Oak Medical Center and Shady Grove Adventist Hospital, both in Maryland. He is also a Managing Member at Advanced Pathology Associates (APA) in Rockville, Md. Cacciabeve earned his medical degree from Georgetown University School of Medicine and is Assistant Professor of Clinical Pathology at George Washington University. Cacciabeve served as site Principal Investigator, and APA was one of four participant sites, for the clinical study that preceded FDA approval of Philips' whole slide imaging system.

About Proscia

Proscia® is an AI software company that is changing the way the world practices pathology to transform cancer research and diagnosis. With the company's Concentriq® digital pathology platform and pipeline of AI applications, laboratories are leveraging new kinds of data to improve patient outcomes and accelerate discoveries. Proscia's team of technologists, scientists, and pathologists is bringing a fresh approach to an outdated industry, helping the world to keep pace with the increasing demand for pathology services and fulfill the promise of precision care.

Proscia's Concentriq digital pathology platform is an enterprise-class software solution for managing image-based workflows in integrated, complex laboratory environments. It provides a single, unified hub that helps labs realize efficiencies, drive down costs, and enable real-time collaboration while serving as a launchpad for the company's specialty-specific AI applications.

To learn more about Proscia, visit **www.Proscia.com** or contact **info@Proscia.com**.

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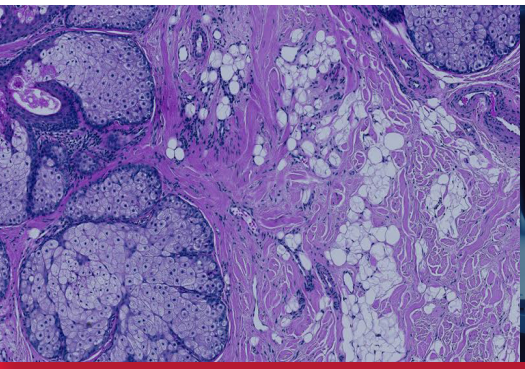

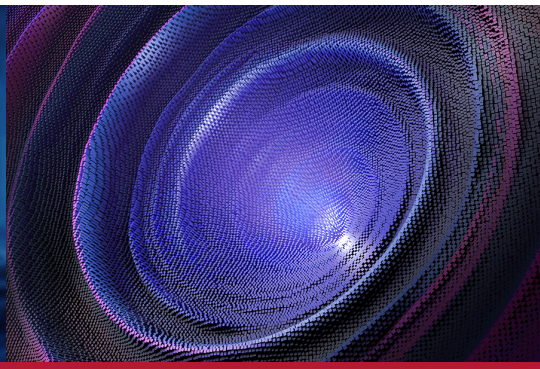

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