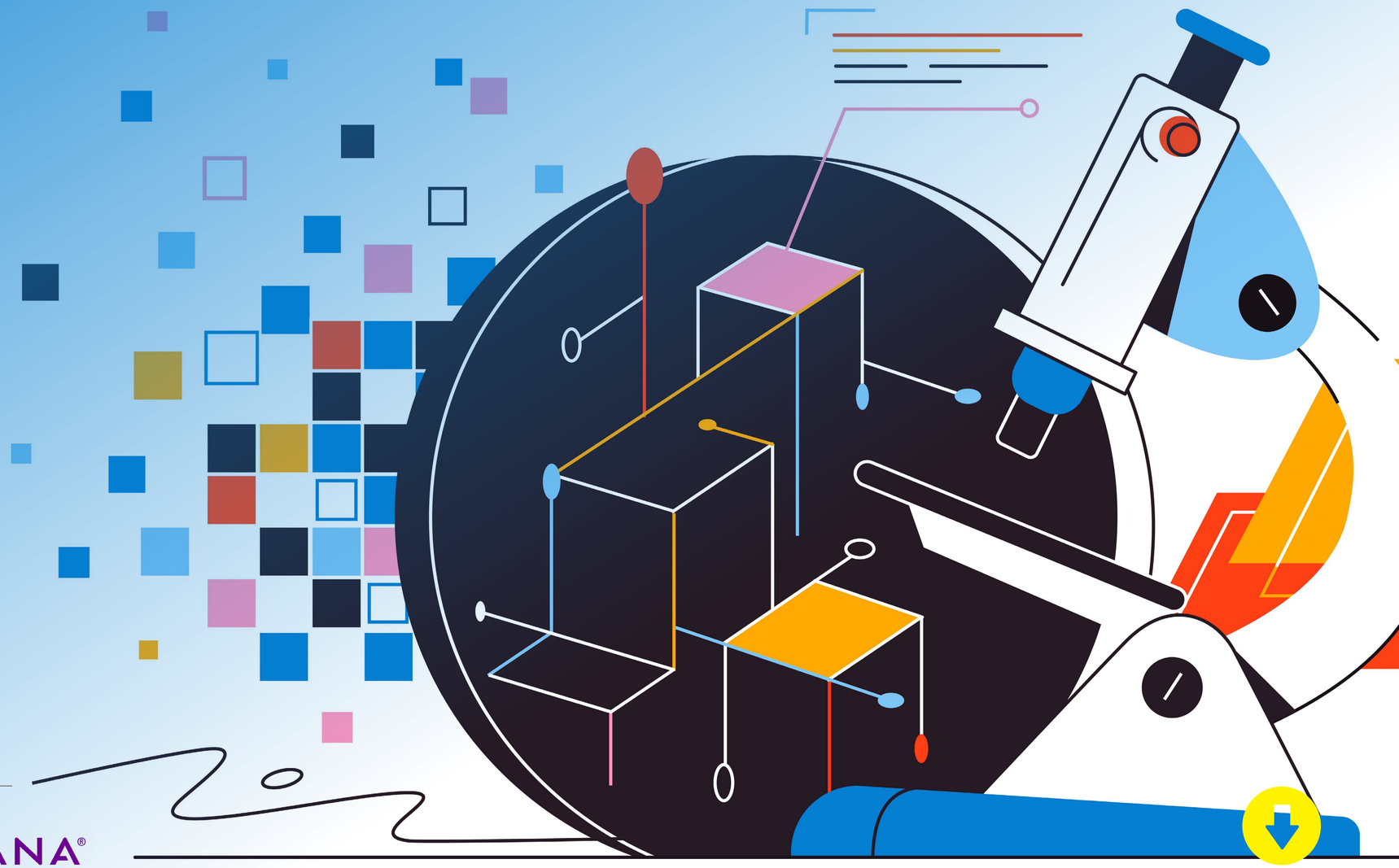
Special Series

Digital Pathology and AI in the Lab

How digital workflows and machine learning tools are enhancing pathology practice



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Machine Learning Predicts Rare Blood Cancer

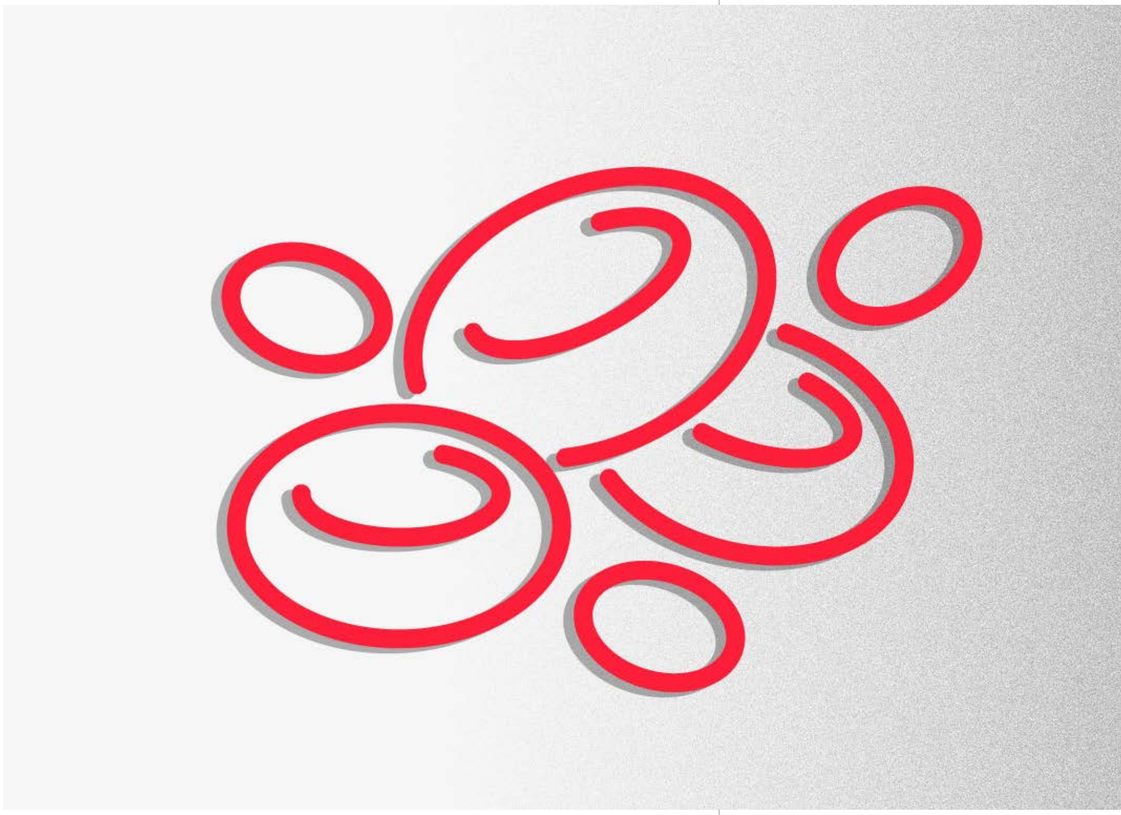
Researchers used complete blood counts parameters to accurately predict polycythemia vera

The Extreme Gradient Boosting algorithm predicted polycythemia vera with 94 percent accuracy using only routine complete blood count parameters, according to a recent study.

The researchers investigated whether polycythemia vera (PV) could be predicted using routine complete blood count (CBC) parameters and machine learning (ML) methods before conducting diagnostic tests such as Janus kinase 2 mutation analysis, erythropoietin (EPO) measurement, or bone marrow biopsy. The retrospective study, published in the Journal of Clinical Pathology, included 1,484 adults presenting with elevated hemoglobin to a hematology clinic between January 2010 and August 2021. Of these, 82 were diagnosed with PV and 1,402 were classified as non-PV. CBC parameters—hemoglobin, hematocrit, white blood cell count, and platelet count—were analyzed using four ML algorithms: Random Forest, Support Vector Machine, Extreme Gradient Boosting, and K-Nearest Neighbours.

Extreme Gradient Boosting achieved the highest predictive performance, with an area under the curve of 0.99, accuracy of 94 percent, and F1-score of 0.94. The analysis indicated platelet count as the most influential variable (42 percent), followed by hematocrit (27 percent), white blood cell count (19 percent), and hemoglobin (12 percent). Statistically significant differences ($p<0.001$) were observed between the PV and non-PV groups for all CBC parameters and EPO levels. Median EPO was 1.77 U/L in the PV group and 9.87 U/L in the non-PV group. Janus kinase 2 positivity was identified in 98 percent of PV cases, and 76 percent of PV patients had bone marrow biopsy results consistent with myeloproliferative neoplasm, compared with 9 percent in the non-PV group ($p<0.001$).

The study was conducted at a single center and used retrospective data. Clinical and biochemical variables beyond the selected CBC parameters were not included, and information on potential confounding factors such as smoking status and comorbidities was incomplete. The authors state that these limitations may affect generalizability and recommend further research with larger, multicenter datasets that incorporate additional clinical variables.



From Glass to Cloud: The Next Leap for Pathology

It's time to embrace new platforms to close workforce gaps and improve diagnostic consistency

John Groth

Pathologists play a key role in accurate diagnoses, treatment plans, and ultimately, patient outcomes. But despite how important our work is, most of us rely on tools and workflows that are stuck in the past.

Glass slides and light microscopes – largely unchanged for more than a century – remain central to anatomic pathology. While reliable, these methods have limitations that affect not only the speed of diagnosis but also collaboration with clinicians and communication with patients. Traditional pathology workflows are slow and cumbersome; for example, physical slides must be shipped for consultations, stored in bulky archives, and reviewed manually. These steps also make it harder to share results seamlessly with other clinicians or to involve patients in their diagnostic journey. The question is: how can we preserve the strengths of established methods while also taking advantage of the opportunities digital technology now provides?

Moving toward digital pathology is not just about upgrading microscopes or scanners. It should represent a full shift in how we approach diagnosis and collaboration. In recent years, pathologists have increasingly adopted digital platforms that allow whole-slide imaging, cloud-based storage, and remote access. My own institution recently launched such a system in partnership with Google Cloud. Cloud platforms hold promise for faster, more accurate diagnoses – especially when combined with AI – and for improved communication across specialties, regardless of location.

This transition mirrors what radiology underwent a few decades ago, when the field moved from film-based X-rays and physical printouts to fully digital imaging stored in picture archiving and communications systems (PACS). That shift transformed radiology, improving efficiency, image quality, and collaboration with the wider care team. Pathology now stands at a similar

"Moving to digital pathology requires more than new technology. It calls for cultural and organizational change in how we work."

crossroads, and the lessons learned in radiology – adopting new technologies while reshaping workflows – can help guide the way forward.

Switching to digital pathology comes with challenges. Interoperability between systems, agreement on data standards, and integration into existing workflows remain significant hurdles. Pathology images are large and complex, so secure and efficient sharing is essential. Implementing these tools also requires training for staff and close collaboration with IT and clinical teams.

From a clinical perspective, digital pathology could also enhance patient engagement. Traditionally, patients have had limited access to their pathology results beyond what physicians communicate. Digital platforms could change this by allowing patients to view their images, ask questions directly, and gain a clearer understanding of their diagnosis. Greater transparency may build trust and improve satisfaction, though it also requires careful communication to ensure findings are explained clearly and sensitively.

In my view, however, one of the greatest advantages of digital pathology is scalability. Digital platforms make it easier to share cases across departments and institutions, giving smaller or resource-limited laboratories access to expert opinions without geographic barriers. Cloud-based systems can handle large volumes of data and users, supporting growth without the need for extensive local infrastructure. This enables laboratories to process more cases efficiently – an important consideration given the rising demand for pathology services and the shortage of active pathologists. Greater scalability could help address workforce gaps, shorten turnaround times, and improve diagnostic consistency across regions.

Moving to digital pathology requires more than new technology. It calls for cultural and organizational change in how we work. Success will depend on leadership within the pathology community, strong collaboration with technology partners, and a commitment to thorough validation and standards.

This is a pivotal moment for our field. By embracing digital tools thoughtfully, pathologists can strengthen accuracy, collaboration, and patient care – ensuring that pathology remains vital, adaptive, and patient-centered well into the future.

John Groth is a pathologist at Endeavor Health, Illinois, USA

AI Won't Save Us – But It Might Give Us Time to Care Again

Burnout is rising and human connection is fading, but technology provides a chance to redefine what "efficiency" really means

Alae Kawam

There's a tension I often feel as a modern medical professional – between how our systems are designed to function and what we, as people, actually want from our work. We operate in a world governed by efficiency, optimization, and measurable outcomes. These are powerful forces that drive organizational success. Yet in a generation increasingly burnt out, I find myself wondering whether we've lost something vital along the way.

This disconnect is visible everywhere. "The Great Detachment," where employees feel emotionally distanced from their work, and the rise of "micro-retirements," where younger professionals leave the workforce to pursue life outside it, both reflect a deep longing for something beyond productivity and profit. I believe these same forces are shaping pathology too – even if we haven't fully acknowledged it yet.

Efficiency has its place. It reduces waste, accelerates workflows, and enables scale. But an overemphasis on streamlining can quietly squeeze out what makes work feel human: depth, creativity, and connection. In a detached and often lonely world, being part of an organization that values meaning and purpose can feel almost revolutionary. Yet for large institutions, "human connection" is difficult to measure, let alone replicate – and when we try to scale it, we risk draining it of its essence.

Still, I don't believe we must choose between meaning and efficiency. The future lies in integrating both. The question I keep returning to is: how do we find that balance in a world that isn't really built for it?

As a pathologist, I imagine a future where technology – especially artificial intelligence (AI) and digital pathology – helps bridge that gap.

First, flexible work arrangements can be transformative. When a pathologist can work remotely, covering multiple locations without ever stepping into a car or bus, it not only saves the lab money but also improves quality of life. It's a win-win.

Second, flexibility gives people room to be whole humans – parents, caregivers, community members. That kind of agency isn't just a perk; it's the foundation of a sustainable, fulfilling workplace.

Third, AI tools can act as co-pilots. Pre-annotated slides, auto-generated reports, and chart summaries can offload the cognitive and physical burden of repetitive tasks. That frees up time and mental space for more nuanced, intellectually stimulating work – like tackling complex cases, mentoring colleagues, engaging with research, or innovating within the field.

And with that reclaimed time, we can do something even more radical: connect. With clinicians. With patients. With our teams. As diagnostic processes become more efficient, the opportunity to lead, manage, and shape the culture of pathology grows. These are the human contributions no AI can replace.

Creating space for connection isn't just good for morale – it's good for medicine. Patients who feel cared for are more likely to seek treatment, return for follow-ups, and trust the system. Communication – between pathologists, clinicians, and patients – may not appear on a KPI dashboard, but it directly improves outcomes.

The future lies in integrating what may seem like opposing values: personal agency and organizational efficiency, optimization and human connection. When we weave them together, we don't just build better workflows – we build better places to work.

It's not a clash between generations. It's a shared desire to do meaningful work – and to do it well. The balance is possible. We just have to design for it.

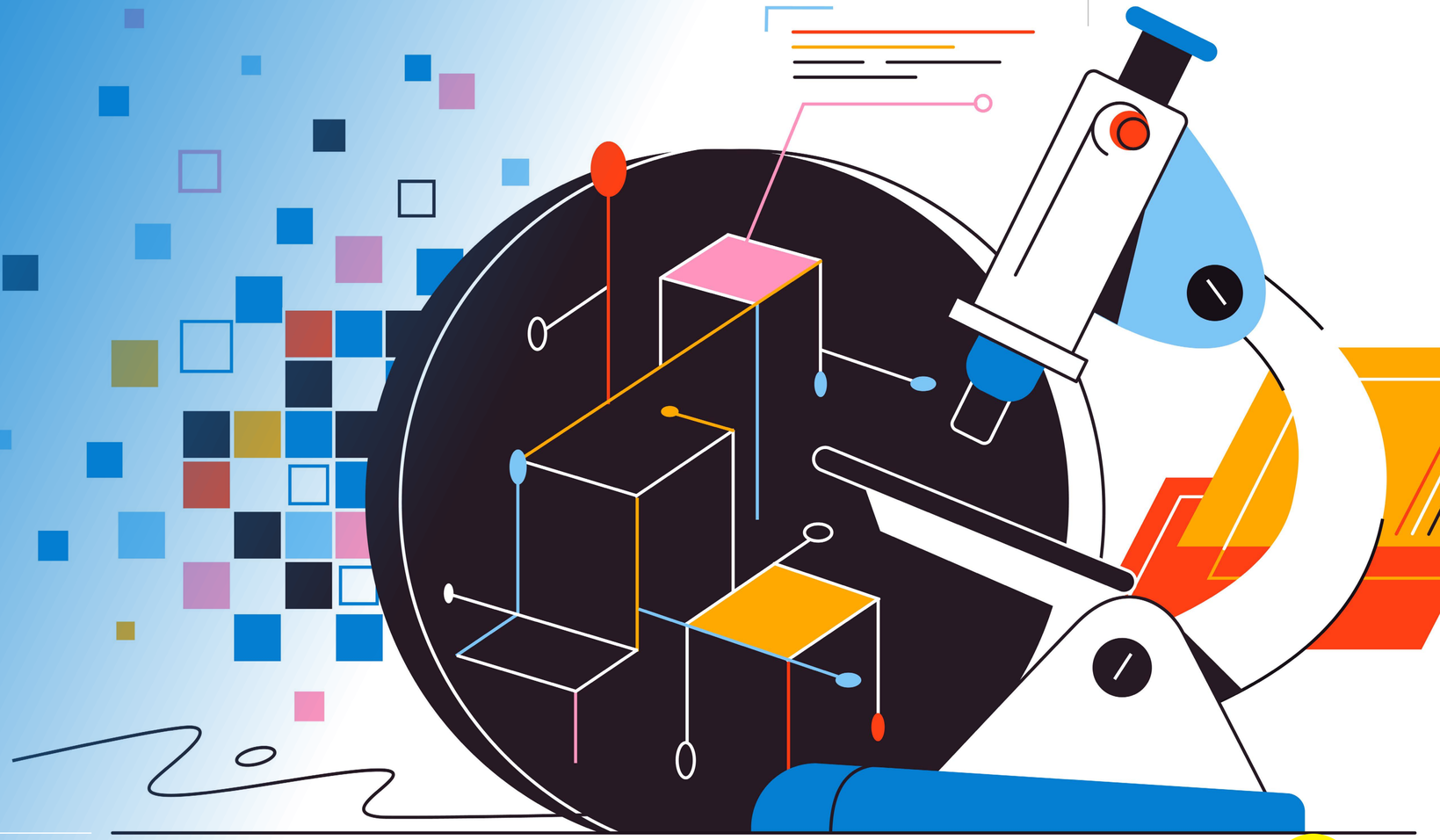
Alae Kawam is Fellow in Genitourinary Pathology at Mt. Sinai Hospital, New York City, USA

Democratizing AI, Globally

A computational pathology and AI center is a must in every pathology department, says Hooman Rashidi

The Computational Pathology and AI Center of Excellence (CPACE) is an AI center in the University of Pittsburgh School of Medicine. With the aim of advancing the field of laboratory medicine by integrating cutting-edge AI technologies in clinical practice and research, the center also promotes continuous learning – and hopes to set the gold standard for innovation in the medical AI landscape.

We connected with Hooman Rashidi, Executive Director of CPACE, to learn more about the work of the center and how its innovations are impacting the practice of pathology.



Meet Hooman Rashidi

Before medical school, I was a graduate student with a focus on bioinformatics at the University of California (UC) San Diego – but I decided to switch tracks and pursue a career in medicine instead. The plan was to enhance medicine through my bioinformatics and machine learning skills. The reality was that I spent many years trying to persuade my institution to introduce bioinformatics and machine learning into clinical practice, but nobody was interested.

Then, about 10 years ago, things changed. I was at UC Davis, working in a group that was building automated machine learning tools. Some of them – such as the Machine Intelligence Learning Optimizer, MILO – have since become commercially available resources, incorporated into various healthcare systems. The CEO and Vice Chancellor of UC Davis invited me to become the AI Director for the whole health system. We built AI models for both laboratory and clinical applications, including sepsis and acute kidney injury.

From there, I moved to Cleveland Clinic to set up an AI center there. Alongside that, we deployed the first no-code AI course, with the aim of democratizing AI literacy for the whole medical landscape.

Finally, I was recruited by UPMC and University of Pittsburgh to create the new CPACE initiative. Alongside that – in my capacity as Associate Dean of AI at the School of Medicine – I was tasked with building an updated, more interactive version of the no-code course to maximize the AI engagement and literacy of our students, faculty, and staff.

Part of that process was writing a new eight-part AI review article series in collaboration with numerous other AI experts from across the country. The series accompanies the no-code e-training, covering everything from the different types of AI, to building custom models, and the regulatory and ethical considerations. Education is deeply rooted in the overall mission of CPACE.

How would you summarize the work of CPACE?

Liron Pantanowitz, Chair of Pathology at UPMC, puts it nicely – we're built to be problem solvers. If people are looking for basic science research in AI, they should not come to us. We are all about translational research. We want the models we design and build to directly impact patient care and improve workflow efficiencies.

That intention is certainly evidenced by our output. Even though CPACE is relatively new to the AI space, we already have eight viable products in our catalog.

Could you elaborate on your machine learning solution for automating the whole-slide image analysis building process?

That is one of the tools that we have filed a patent on. It's an automated machine learning framework for building, validating and deploying

whole-slide image analysis for specific disciplines.

Traditionally, building a model for this kind of application – say, to detect prostate or colon cancer, or predict PD-L1 status – can take anywhere from several months to over a year. That's because whole-slide images are massive files, and the process of creating triage models is extremely resource-intensive.

Given my background in automated machine learning, our goal was to streamline this entire pipeline – from model creation to clinical deployment – using a fully automated framework. We designed it to work across different pathology disciplines, with the ability to rapidly generate highly specialized models.

And that specialization matters. Rather than developing one generalized model to handle multiple cancer types – that might not perform as well – we build narrow, task-specific models. It's the same logic we apply to human expertise: a specialist pathologist typically outperforms a generalist when it comes to their area of focus. The same should be true for AI. So, our tool builds specialist models that can deliver much stronger performance within their domain.

Because the process is now automated and runs on our high-performance computing infrastructure, what used to take months we can now complete in just a couple of days. Instead of producing four or five models a year, we're capable of building hundreds. That scalability is a potential game changer for pathology, enabling more triage tools and AI-assisted workflows to support pathologists.

It's important to stress that we see these tools as assistive, not autonomous. We believe firmly in a "human in the loop" model. These AI solutions help pathologists with the initial assessment, but the final interpretation is always made by a board-certified pathologist – often in conjunction with other diagnostic tests and clinical data.

That automated slide analysis tool is a great example of a non-generative AI application with real-world clinical utility. It's one of many innovations we're working on to advance pathology with scalable, intelligent tools that make a meaningful difference.

What were the main considerations for CPACE in designing open-source chatbots for laboratory medicine?

We've developed several generative AI platforms, including one called Pitt-GPT+ and a newer one called Nebulon GPT. The biggest priority for both is patient privacy.

If you've ever used a chatbot like ChatGPT, you'll know that your data is shared with a third-party cloud provider – whether it's OpenAI, Google, or Microsoft via Azure. That's fine for many use cases, but in healthcare or any setting involving sensitive data – like patient information or proprietary content – you have to be cautious. Anything you input could potentially be used to train future models. So, if privacy matters, that's a major concern.

Now, let's say privacy isn't an issue and you're okay with your data being stored privately through Microsoft, for example. You still run into a second issue: cost. If you're building a custom chatbot and hosting it through a commercial platform, every user interaction incurs an API or usage fee. That can become financially unsustainable, especially if you're scaling to hundreds of thousands of users.

The tech world follows a familiar playbook. At first, services are attractively priced to get you hooked. But over time, either costs creep up or your user base grows, and the total cost becomes prohibitive.

This is why open-source models are so exciting. Platforms released by companies like Meta are now incredibly capable – on par with some closed-source models. The open-source approach allows you to deploy the model on your own infrastructure, completely privately, with no API fees – just the cost of running your own servers. We've already built frameworks around this approach, offering fully private, cost-effective alternatives to commercial generative AI tools.

In addition to the above, responsible use of generative AI tools by individual users is also a must-have within most systems. At Pittsburgh, we've set some clear expectations around the responsible use of generative AI within the School of Medicine, thanks to a great

"That's what makes it so powerful – it stays in its lane and focuses solely on your uploaded materials. The key features are privacy and cost – everything about it is designed to keep your data secure and the costs low."

framework created by my colleague, Jason Rosenstock. We call it the DVP rule:

D is for Disclose. If you're using generative AI, be transparent about it. For example, if you used ChatGPT to generate an outline **before writing your manuscript or to create an image, disclose that** upfront. People should know which parts were AI-assisted and which parts were your own work.

V is for Verify. You must verify everything the AI outputs. These models are powerful, but they're not perfect – they can and do make mistakes. It's your responsibility to fact-check and ensure the information you use is accurate and trustworthy.

P is for Protect. Be mindful of what you upload. Don't share sensitive data, copyrighted material, or anything that could violate patient privacy laws like HIPAA. If you're in doubt, don't upload it.

These principles are the foundation of how we teach our students, faculty, and staff to work with generative AI responsibly. And they're part of why we've invested in private chatbot infrastructure. When the platform is private and well-contained, the risk of accidental breaches drops significantly. That's where Pitt-GPT+ and Nebulon GPT stand apart – they offer control, security, and relevance in a way that traditional public models just can't.

How are PITT GPT+ and Nebulon GPT used in clinical or operational settings?

With Pitt-GPT+, users can upload their own documents – say, 1,000 laboratory reports – and interact with them directly through the chatbot. It has a much lower tendency to stray into unrelated topics or pull in external information. If you ask something outside the scope of your documents, it will simply respond, "I don't know." That's what makes it so powerful – it stays in its lane and focuses solely on your uploaded materials. The key features are privacy and cost – everything about it is designed to keep your data secure and the costs low.

Nebulon GPT is designed for more general-purpose queries. If you want to ask questions like you would with ChatGPT – based on global knowledge, not your own files – but still want to do so in a private environment, that's where Nebulon GPT comes in. It is so called because, like a nebula in space, it's dark and private. The whole idea is to allow users to run queries securely and confidentially without sharing data with external platforms.

That said, I want to be very clear: at this point we don't advocate using these tools for direct patient care or allowing patients to ask clinical questions. These models, while incredibly useful, can hallucinate – they might present inaccurate information or cite unreliable sources. Pitt-GPT+ is slightly different in that it's grounded in your own uploaded documents, which improves reliability. Still, these tools are meant for practitioners, not patients

CPACE has also released a machine learning tool for generating pathology reports. What impact is that having on laboratory workflows?

The first two users of the report-writing tool were actually me and my colleague, Matthew Hanna. He applied it in breast pathology

and I used it in hematopathology – so I can speak from experience. The reason people really like this tool is because it addresses several long-standing challenges in pathology reporting.

The first is time. Bone marrow reports, for instance, are lengthy – typically three to five pages – and they take a long time to write. Even for an experienced hematopathologist like me, a single case could take 25 to 30 minutes. That kind of time commitment adds up quickly, impacting work–life balance. Fatigue also becomes a real concern, and when people are tired, the risk of errors increases – which can have serious implications for patient safety.

Second, there's a lack of standardization. Reports vary significantly between institutions and even between pathologists. While we try to keep formats consistent, in reality, the content is often scattered and inconsistent.

Third – and this is a big one – traditional dictation methods like Dragon software or transcriptionists don't offer in-document quality control. This is especially relevant for longer reports. If I accidentally write, on page one, that a patient has 3 percent blasts, but, on page three of my microscopy section, the correct number of 37 percent is stated, there's no internal system checking for that inconsistency. That's a major risk, especially for patients on clinical trials. Mistakes like that can cause real harm and require report amendments.

This is where generative AI, combined with rule-based systems, comes in. With our model, what used to take 25–30 minutes now takes under five. It runs automatic quality checks throughout the report to catch inconsistencies. Just as importantly, it helps ensure that structured data is captured more accurately, which benefits downstream analysis and clinical decision-making.

Not everyone will adopt this immediately – and that's okay. Some are naturally hesitant. But I believe adoption will grow as clinicians see their colleagues finishing work at 4:30 while they're still typing away at 7:30 or 8:00. The time savings alone will drive adoption, but so will improvements in report quality and patient care.

Like any innovation, adoption follows a pattern: early adopters, early majority, late majority, and eventually the laggards. And I do believe even the laggards will come on board – especially once regulatory bodies start mandating these tools. That day is coming. But for now, we're in the early adoption to early majority phase – and it's exciting to see the momentum building.

How is the work of CPACE funded?

We're not a startup; we are a purely academic venture, fully funded through grants and philanthropy. Thankfully we are well funded, which means that, despite all the recent freezes on research and hiring in the US, we can move forward with our mission. We also generate income from running industry-sponsored studies.

Additionally, as our products become licensed, that will also generate a revenue stream for CPACE to continue and grow its mission.

What does the future hold for CPACE?

We plan to move ahead, full force, with democratizing AI globally. We want what we do here to be translated to other centers of excellence. We're firm believers that a computational pathology and AI center is a must in every pathology department.

To that end, we're very open to sharing our knowledge and expertise with other centers. Recently, we were visited by a group of colleagues from UC San Francisco, seeking advice on setting up their own AI center, which is very exciting to see.

That's one of our primary goals: sharing our knowledge and helping other places to establish similar setups. We want to make sure that our whole discipline stays ahead of the game.

Crystal Clear: Why Image Quality Matters

How achieving diagnostic-ready image quality during scanning transforms pathology workflows and unlocks the future of computational pathology with AI

By Matthew Wildrick

In the race to digitize pathology workflows, laboratories face a critical decision that will determine their success for years to come: whether to prioritize image quality during the scanning process or settle for post-scan optimization. This choice isn't just about technical specifications – it's about fundamentally reimagining how digital pathology should work.

The conventional approach treats image capture and quality assurance as separate processes. Slides are scanned quickly, then reviewed manually for quality issues, with problematic areas flagged for rescanning. Given an industry average of 5% rescan rate, this translates to one in twenty slides being rescanned, significantly increasing turnaround times. This workflow creates bottlenecks, introduces subjectivity, and ultimately compromises diagnostic confidence.

For institutions embarking on their first digital pathology journey, this approach can be detrimental to the advancement of a digital pathology program. Senior pathologists who have spent decades mastering the microscope often approach digital pathology with understandable skepticism. When they encounter suboptimal image quality – blurry areas, poor focus, or missing critical details – it reinforces their belief that digital pathology cannot match the diagnostic precision they've achieved with traditional microscopy. This skepticism can set back programs by months or even years, due to the resulting lack of champions for the adoption of digital pathology.

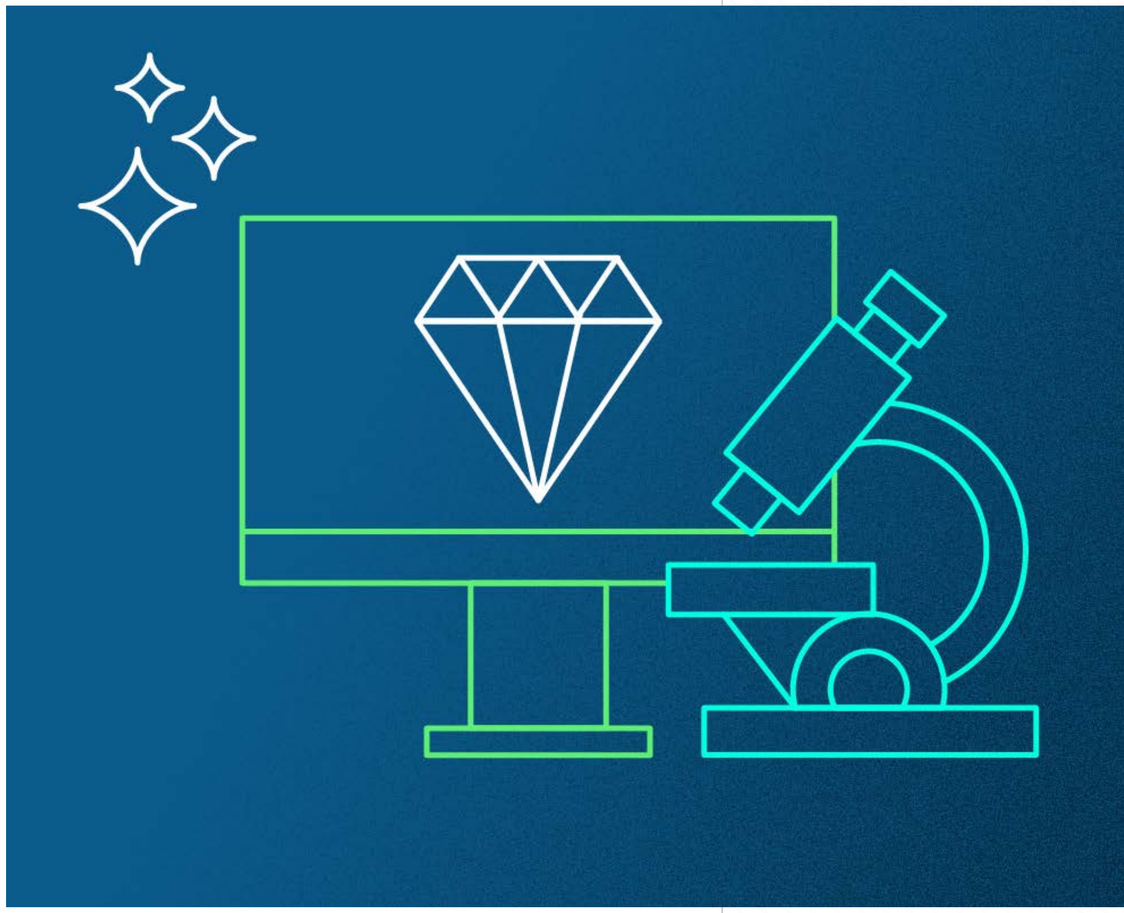
We think there is a better way; let's dive in.

The technical imperative: quality at the source

Modern digital pathology systems can now achieve diagnostic-ready image quality during the initial scan through three critical technological innovations working in concert: edge computing, real-time volumetric imaging, and inline scanning algorithms powered by AI.

Edge computing brings sophisticated processing power directly into the scanning system, enabling real-time analysis without the latency and security concerns of cloud-based approaches. This architecture allows the system to make autonomous decisions about focus, exposure, and resolution while the scan is in progress, rather than after the fact. The result is sub-second response times for quality assessment and immediate correction of imaging issues.

Instead of relying on post-scan review, this architecture performs continuous quality evaluation during scanning, analyzing multiple parameters simultaneously to ensure diagnostic-ready images without manual intervention. Advanced AI algorithms powered by edge computing distinguish between actual tissue and artifacts such as pen



marks, bubbles, or debris, ensuring complete specimen capture while optimizing scanning parameters for each region.

For particularly challenging use cases, where wet preps, sparse slides, and varying sample thickness create significant digitization hurdles, real-time volumetric imaging can analyze each field of view, mimicking the fine focus of a microscope. This enables the capture of Z-stacks and the fusion of the best pixels from multiple focal planes to produce high-quality images. This Z-stack fusion process combines the sharpest elements from each focal plane, creating a single, fully-focused image that preserves all critical diagnostic details. The system can retain original Z-stacks for further review in areas where AI identifies significant objects, providing pathologists with the depth of information they need for accurate diagnosis.

And last but not least, inline scanning algorithms powered by AI adapt to specimen characteristics, automatically adjusting focal planes, resolution, and capture parameters based on tissue type and preparation quality. In sparse Z-stacking, Z-stacks are captured only in areas where inline algorithms detect objects of interest. These algorithms intelligently optimize the number of focal planes captured based on specimen complexity.

This approach eliminates the need for pre-scan preparation while ensuring optimal imaging conditions for each case. The system handles challenging specimens – thick tissue sections, cytology preparations with varying focal planes, and specimens with preparation artifacts – without requiring manual intervention.

The operational reality: why quality changes everything

The impact of achieving quality during scan time extends far beyond technical specifications. It fundamentally transforms laboratory operations in ways that directly affect patient care and organizational efficiency.

Consider two contrasting scenarios that laboratories face when implementing digital pathology:

Scenario 1: The Traditional Approach

A technician loads slides into the scanner and initiates batch processing. After scanning completes, a quality control specialist manually reviews each image, flagging some slides with focus issues, some with missing tissue areas, and some with staining artifacts. Flagged slides must then be retrieved from storage, rescanned, and re-reviewed. The process repeats until all slides meet quality standards. Meanwhile, pathologists wait for cases to be ready for diagnosis, creating a bottleneck that can significantly extend case turnaround times. In some cases, when the quality control staff is overwhelmed, pathologists themselves must perform the final quality assessment – an expensive use of their time that further delays end-to-end processing.

Scenario 2: Quality at the Source

The same set of slides is loaded into an intelligent system that performs real-time quality control during the scan. The system automatically corrects focus issues, identifies missing tissue areas, and adapts to staining variations – all while the scan is in progress. When scanning completes, slides are immediately ready for pathologist review, allowing them to begin diagnosis immediately, reducing case turnaround times from days to hours.

The difference between these approaches is profound. Autonomous quality intelligence embedded directly into the scanning process reduces manual quality control requirements by 90%, allowing staff to focus on higher-value activities. First-pass success rates exceed 99% across all specimen types, with near-zero rejection rates on whole-slide images.

The operational benefits are immediate and measurable. Laboratories

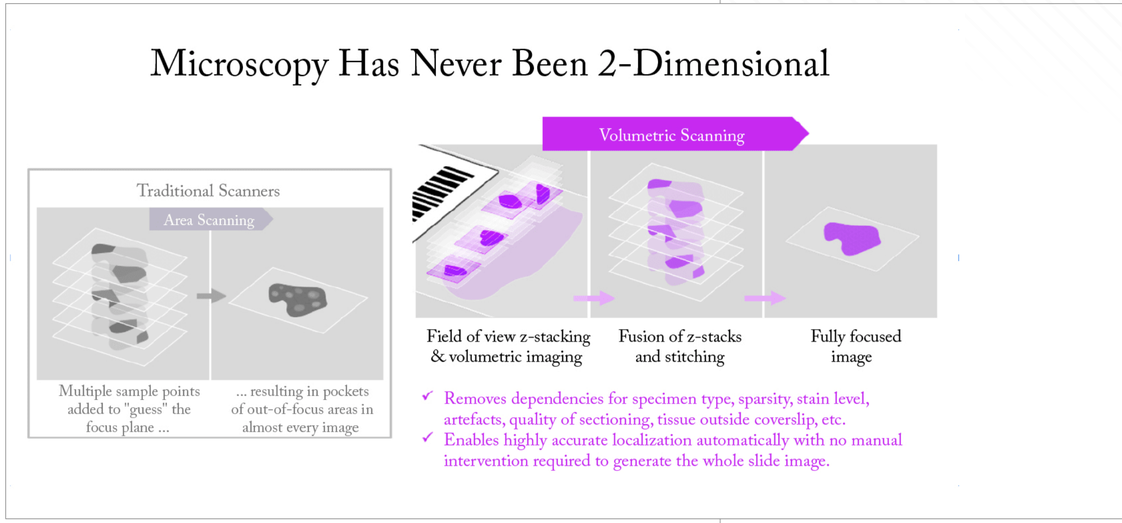


Figure 1: Highlighting the traditional challenges to enable digital imaging for challenging slides, and the benefits of volumetric imaging that's used to provide greater quality, independent of the specimen type. Credit: Pramana

implementing this approach report a significant reduction in manual labor, given more than a 20x reduction in slide rescans. As a result, case turnaround times improve dramatically, with consult cases moving from 8-day delays to same-day completion. This results in increases in staff satisfaction as technicians can focus on complex cases and process improvement rather than routine quality control tasks.

With increasing difficulty in recruiting and retaining top talent, labs need solutions that maximize productivity. By automating routine quality control tasks and eliminating the frustration of repetitive rescanning, labs can empower their experienced technicians to dedicate their expertise to higher-value diagnostic work. The dramatic reduction in manual quality control can deliver high throughput, while the improved workflow satisfaction can help attract and retain the skilled professionals who are increasingly difficult to find in today's competitive market.

The technology's ability to handle traditionally difficult specimen types across multiple pathology subspecialties eliminates the operational challenges that have prevented many laboratories from digitizing these critical applications as well. In cytology, where three-dimensional cell clusters and varying focal planes have historically resisted reliable digitization, dynamic Z-stacking technology captures every cell cluster with optimal clarity regardless of its position in the Z-axis. For hematopathology, where nuclear details and chromatin patterns are critical for accurate diagnosis of hematologic malignancies, advanced focus algorithms ensure crisp visualization of cellular details in bone marrow biopsies and peripheral blood smears. In anatomic pathology, the system adapts to specimen variations automatically, handling everything from routine tissues to challenging core biopsies with consistent quality.

Even in microbiology – where slides with varying sample thickness create significant digitization hurdles – the technology can capture Z-stacks and fuse the best pixels to produce high-quality images. By bringing intelligence into the digital scanning process, labs can achieve diagnostic-ready images across all subspecialties, bringing the full benefits of digital pathology to previously underserved areas like parasitology, gram staining, and AFB slides.

The hidden costs of compromising on quality

Organizations that choose to prioritize speed over quality during scan time often underestimate the long-term costs of this decision. The initial savings in scanning time are quickly offset by the operational burden of manual quality control, increased rescan rates, and the diagnostic uncertainty that comes with suboptimal images.

Manual quality control processes introduce subjectivity and variability that can impact diagnostic confidence. This variability creates risk in diagnostic interpretation and can lead to inconsistencies in patient care. Even when dedicated quality control specialists perform this work, the process can remain subjective according to workload, fatigue, or other factors. Pathologists who are forced to perform quality control not only waste their valuable diagnostic time but also introduce additional subjectivity based on their individual diagnostic priorities and experience levels.

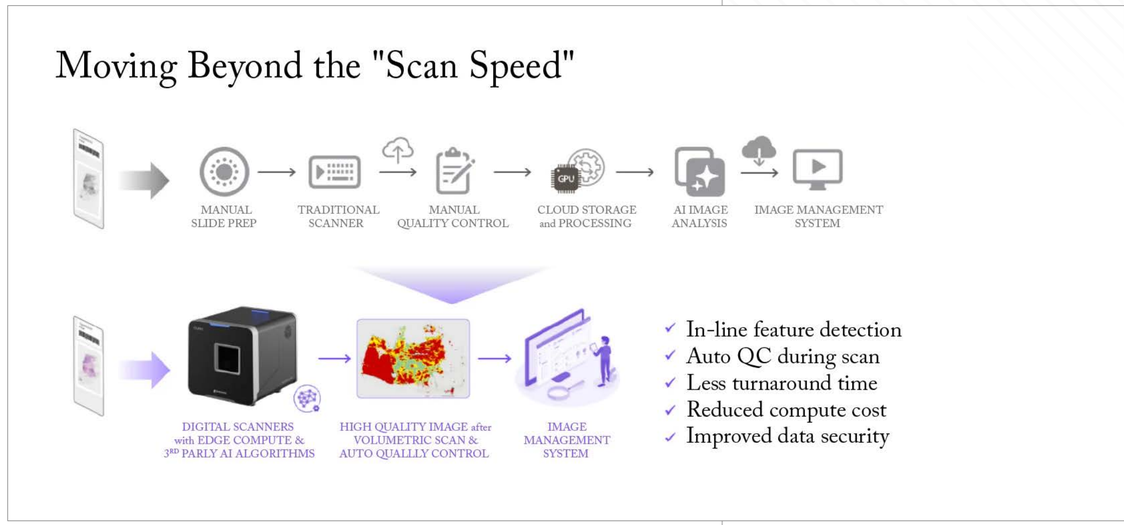


Figure 2: Highlighting the traditional challenges in whole slide imaging workflows, and the benefits of next-generation solutions that are designed to deliver the highest quality imaging while improving case turnaround times. Credit: Pramana

The financial impact extends beyond direct operational costs: suboptimal image quality can result in errors, leading to delayed treatment and potential patient harm. The cost of a single diagnostic error far exceeds the investment in quality imaging technology.

Making the right choice

Perhaps most importantly, achieving quality during scan time positions organizations for the future of computational pathology. High-quality images provide optimal training data for AI applications, enabling the development of sophisticated diagnostic algorithms.

Real-time analysis capabilities create immediate value while building the foundation for future healthcare applications powered by computational pathology.

This architecture sets the stage for expanded digital adoption in areas like bacteriology, parasitology, and cytology, where object-level resolution in three dimensions can be helpful for diagnostic reads. The ability to run third-party AI algorithms directly on the scanner during the scanning process represents a fundamental shift in how digital pathology systems can be deployed and utilized, making advanced digital pathology accessible to a broader range of laboratories and applications.

For laboratories considering digital pathology implementation or upgrades, the question isn't whether to prioritize quality during scan time – it's how quickly they can make this transition. The organizations that act decisively will gain significant competitive advantages in efficiency, diagnostic confidence, and future readiness.

The choice is clear: invest in quality during scan time now, or pay the price of compromise later. The organizations that choose wisely will find themselves leading the transformation of pathology practice, while those that hesitate will struggle to catch up.

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Cash for Data Cohorts

Exploring the economic benefits of digital pathology

The initial outlay for digital pathology technology might seem overwhelming, but the data it could generate might just prove to be a valuable asset – one that could help recoup some of the cost.

Proscia recently published a report that acknowledges some of these data demands and their potential for revenue generation.

Here, Derek Welch, President and Chief Medical Officer at PathGroup, shares some thought-provoking examples.

What are some of the aims and objectives of digital diagnostic networks?

In the US healthcare market, there is currently no incremental reimbursement for adopting digital pathology. That leaves many laboratories asking the same question: how do we justify the substantial costs of going digital?

If we look outside the clinical lab, pharmaceutical companies are highly interested in digital pathology because it provides a new type of asset: pixelated images of disease in patients. In oncology, in particular, these digital images can unlock insights beyond what the human eye can detect and accelerate drug development by providing faster, cheaper access to real-world data.

Owning such digital assets at scale makes clinical service providers attractive collaborators for industry. Currently, only about 7 to 10 percent of glass slides in the US are digitized, meaning the overall pool of digital pathology data is still small. This scarcity further increases the value of laboratories that are already digital and positioned as part of a broader network.

Being part of this digital ecosystem places a lab in the unique position of being able to contribute to and benefit from pharma collaborations – both AI development studies, and other research opportunities. It transforms pathology from an analogue process into a language of pixels – zeros and ones – that can be analyzed, shared, and monetized in entirely new ways.

How might labs be able to work with biopharmaceutical partners in the real-world data space?

This is an evolving space, but it is clear that digitally-enabled labs have the ability to create real-world data cohorts that are valuable to pharmaceutical companies. “Cohort” is the key word here, referring to a set of patient cases with high-quality, de-identified digital images accompanied by metadata and, ideally, additional pathology information such as molecular sequencing results or targeted PCR analyses.

Pharma companies need to identify patient populations for clinical trials quickly and cost-effectively. By incorporating digital pathology images into the patient record, laboratories create a new parameter that can be searched and filtered using computational pathology tools.

For example, a lab that sees 15,000 oncology patients a year could rapidly filter cases to identify those with non-small cell lung cancer who are positive – or negative – for a specific molecular defect. This capability allows pharma partners to accelerate trial enrollment and, ultimately, the development of new therapies.

What opportunities might be available for AI development partnerships?

Many companies are developing clinically useful algorithms aimed at reducing human error in diagnostics. They are based on the idea that the algorithm combined with the human being creates a better outcome. Digital pathology labs provide the ideal test-beds and training grounds for such applications.

On the clinical research side, oncology is the key area for partnership opportunities. AI is being developed to uncover novel insights about tumors that can speed drug discovery and reduce costs. Traditionally, drug development is a slow and expensive process. The idea of applying computational algorithms "at the push of a button" to large oncology datasets is highly attractive, offering the potential to identify targets, biomarkers, or patient subsets much earlier and more efficiently.

Companies are emerging that specialize in combining sequencing data from solid tumors with image-based data, building sophisticated algorithms that extract new, actionable information from these datasets. Their work illustrates how AI straddles clinical care and pharmaceutical R&D – driving advances in both areas.

What are some of the ways in which labs could provide precision medicine services to pharmaceutical companies?
For digital labs operating at scale, the key question is: what do we do with these images once they've been signed out?

Rather than purging files, labs can build de-identified oncology image repositories enriched with additional data – molecular results, PCR assays, and other pathology metadata.

Pharma's needs vary. Some partners may want full sets of images for algorithm development, while others may only require representative samples for training AI filters to detect specific mutations. Some research requires data from specific patient demographics to avoid bias in their cohort data.

At PATHGroup, we have already engaged in projects along these lines, both independently and in collaboration with Proscia and other research entities. Some of these focus on supporting pharmaceutical development, while others are aimed at building foundation models in digital pathology – large-scale AI tools that can be adapted across applications.

By organizing and retaining their "digital exhaust," as Proscia CEO David West has called it, labs can transform routine diagnostic output into a valuable research asset.

Could you share any case studies of digital pathology partnerships from your own labs?
Lung cancer research seems to be the area with the most demand for these kinds of collaborations. We've already participated in a couple of lung cancer studies in collaboration with Proscia. Following strict data compliance rules, we were able to supply data packages for cohorts of patients with non-small cell lung cancer. It was used in both AI and drug development.

We've also worked with some innovators of large-scale foundation models that needed a variety of digital images to assist with building the AI capabilities. If you think of a stairway, we're the first step – digitizing patient data – the foundation model developers are in the middle, and the end users sit at the top.

How might membership of a diagnostic network help labs to reshape their economics?
There are opportunities for offsetting at least some of the costs of digital infrastructures today. Successful collaborations do require some effort – it's not a case of just sharing images. Sophisticated technical solutions, such as AI-powered clinical research platforms, might be required. But participating in the real-world data space does create opportunities to tangibly improve patient care and also create a revenue stream.

Whilst it might not be possible to recoup the full cost of digital investment in the current climate, economics suggest that the costs will fall as the market establishes itself. The first CD players cost around $1,500, and 10 years later they were available at a tenth the size for less than $50.

In the US, medical insurance companies have maintained for decades that they will reimburse according to quality of patient outcomes. In today's labs, where it becomes possible to prove the quality benefit of pathologists working in conjunction with AI, I'm hopeful that eventually there will be revenue streams from the use of AI.

Saying that, the physician side of me really hopes that healthcare trends towards more and more entities becoming digital. Because it's a good thing for patients.

How Digital Pathology is Transforming McLaren Health Care

Bringing the pathologist out of the shadows

Q&A with Dr. Ali Gabali, MD, FCAP
Chairman and Chief Medical Officer of Pathology and Laboratory Services, McLaren Health Care-Karmanos Cancer Institute

What were the biggest operational or cultural hurdles you encountered during this transition? How did your team overcome them?
We listened. We didn't push; we invited. We created a safe environment where questions weren't just allowed, they were welcomed. We paired experienced pathologists with digital champions, not to "convert" them, but to support them. We brought vendors in for in-person demos across McLaren sites. We sat side-by-side at the sign-out. We compared diagnoses between glass and digital and we validated thousands and thousands of slides, until confidence replaced doubt. And what truly changed the game was when we shifted the focus from technology to patient care. We showed how this transition wasn't about replacing anyone, it was about helping us serve faster, connect better, and ensure that no patient's sample had to wait.

When our pathologists saw that digital tools could help them serve patients faster, collaborate more effectively, and still retain full control over the diagnostic process, something clicked. Pride replaced hesitation. And that's when the culture changed.

How does digitized pathology data reshape collaboration between hospitals, specialists, and even external partners within your integrated network?
Before we went digital at McLaren, collaboration often felt like a luxury. Sharing slides between hospitals took days. Getting a second opinion meant courier services and waiting for days. Now? Everything's different. Digital pathology has transformed how we work together. We're no longer a group of isolated physicians sitting in the basement of the hospital, we're one cohesive, connected team. Subspecialists can weigh in across hospitals in real time. Multidisciplinary tumor boards have immediate access to full digital slides, complete with annotations and shared viewing. Our turnaround times have improved, but more importantly, our communication has become seamless.

McLaren is now collaborating more effectively with outside institutions, academic centers, reference labs, and international partners. Digital access has erased geographical barriers and opened the door to second opinions, joint research, and richer educational opportunities. Our younger pathologists and medical technologists now learn from a larger pool of cases, and our patients benefit from collective expertise.

But the most profound change is how our pathologists feel. They're not working in the shadows anymore. They're part of the real-time care team, visible, valued, and engaged. That's what digitization has given us. Not just better technology, but a better way to practice medicine.

This journey has reshaped the practice of pathology at McLaren. I am proud of how far our team has come. This transformation was more than technical, it was human, and deeply meaningful.

Explore more at:
go.roche.com/digitalpathology-us-tpeb

Computational Pathology: The Next Generation of Companion Diagnostics

Why AI shouldn't be an afterthought in your digital pathology journey

Landon J. Inge, PhD, Medical Affairs Lead Global, Clinical Development and Medical Affairs Roche Diagnostics Solutions

Mark Hellewell, International Product Manager Personalized Heath Care Solutions Roche Diagnostics Solutions

On April 25th, 2025 Roche announced that TROP2 NMR, a novel computational pathology device, was granted FDA Breakthrough Device Designation, sparking a vital discussion about its role in revolutionizing companion diagnostics in personalized healthcare and what labs can do to prepare for future computational pathology-based tools.[1]

Why do you think pharma is interested in using computational pathology image analysis in clinical trials?
LI: I think a lot of this is due to published concerns around pathologist concordance for companion diagnostic IHC assays. For some companies, computational pathology represents a potential avenue for standardization and reduced variability of IHC assessment for clinical trials. And I think for pharma, if these improvements come in parallel with improved efficacy, that collectively provides substantial benefit for pharma. However, broad implementation of digital pathology still remains a hurdle for getting computational pathology used in routine clinical labs.

How does the Breakthrough Device Designation (BDD) reflect the FDA and other global health authorities' current thinking about computational pathology-based companion diagnostics?
MH: Everything we're hearing from the FDA focuses on ensuring that this is an end-to-end device, to guarantee quality and reproducibility. And that's how we're approaching all our products now, which involves providing an end-to-end solution, from staining all the way through to image analysis.

Obviously, there are many options on the market from a digital pathology perspective, but there's also a lot of variation between image types. And this can really impact the way a scoring algorithm could produce outputs. So, particularly in these early stages of computational pathology, it's important to show that we have this end-to-end device, in which we can control every component to ensure that we have that quality.

What can labs do to prepare for future computational pathology CDx devices?
LI: What labs need to start understanding and preparing for, outside of just infrastructure build, is the quality of the IHC and the quality of the slides. All those factors that may seem routine for the lab staff are going to be critically important in making sure that they're of high quality in order for these algorithms to work. There is already a fair amount of information out there about how variations in staining can throw off algorithms. So we, as a laboratory staff, are really going to need to be much more on top of how they're preparing those slides, monitoring the fixation and other pre-analytics associated with the tissue, in order to make sure that these algorithms can run successfully.

Reference
1. *Roche granted FDA Breakthrough Device Designation for first AI-driven companion diagnostic for non-small cell lung cancer*

The conversation continues here:
go.roche.com/computational-pathology-tpeb