

Digital Pathology Can Be Transformative for Labs

► Pathologists have opportunity to innovate with this technology to improve patient care

►► **CEO SUMMARY:** *Across the nation, pathologists are at a crossroads. Now that the FDA has cleared a digital pathology and whole slide imaging (WSI) system for use in primary diagnosis, should they adopt this technology sooner or wait until later? One pathologist who has worked with WSI for many years shared the lessons learned in his lab. Pathologists should recognize the potential of combining this technology with algorithms and robotics to make earlier and more accurate diagnoses, he said.*

PATHOLOGISTS ARE ONE STEP CLOSER TO daily use of digital pathology and whole slide imaging, following the FDA's clearance of the nation's first digital pathology system and whole slide images for use in primary diagnosis.

In April, the FDA announced that the **Philips** IntelliSite Pathology Solution (PIPS) could be marketed for primary diagnosis in the United States. This is the first whole slide imaging (WSI) system the agency has cleared that allows diagnostic interpretation of digital surgical pathology slides prepared from biopsied tissue without traditional optical microscope review. (See *TDR, April 24, 2017.*)

Now that a digital pathology system has regulatory clearance, all anatomic pathology groups in the United States must confront the new reality: the era of primary diagnosis using whole slide images has begun. In this era, pathologists have a conundrum: Should their groups be early-adopters of digital pathology or should they wait until use of whole slide imaging is more common?

To answer this question, THE DARK REPORT sought out a pathologist who has

extensive knowledge of many digital technologies and software development efforts used in research labs and academic centers: John Gilbertson, MD, who is Director of Pathology Informatics at **Massachusetts General Hospital** in Boston. He is also an Associate Professor at **Harvard Medical School** and Associate Chief for Informatics at **MGH**.

► Digital Path As Disrupter

Disruption in anatomic pathology will not come simply from replacing glass slides and the traditional microscope with whole slide images, he said. It will come because the digitization of these images creates the opportunity to use digital technologies to analyze the images in new ways that cut time to diagnosis and generate new information about the tissue being analyzed. That can mean earlier detection of disease and a more precise diagnosis.

"When a pathology lab can digitize most or all of its slides rapidly, automatically, and in high fidelity, it can then apply computational power and network connectivity to those digital slides," observed Gilbertson. "The whole slide image allows

a pathologist to view that slide, to use algorithms to analyze that slide, or send the digital images of those slides out to all the computers across its network.

“Also, pathologists will find additional uses that draw upon the computational power and network connectivity that have been the power drivers of innovation, discovery, and productivity across a wide range of industries,” he added.

Gilbertson advised pathologists to recognize that the technology trends and market forces transforming all industries, including healthcare, will propel swift adoption of whole slide imaging in anatomic pathology. As change happens, pathology groups must be ready to acknowledge this change and act decisively to protect their clinical relationships while delivering the additional value needed to thrive as fee-for-service payment disappears.

➤ Using Artificial Intelligence

“Today, my pathology organization is looking at our ability to get involved early with artificial intelligence,” stated Gilbertson. “At this stage, our primary interest is in different ways we can use digital imaging to change how our pathologists diagnose disease. Changing workflow is a benefit, but not the emphasis. The change in workflow will certainly come after we have determined how we will change the diagnostic step.

“These are important reasons why I say this is a major advancement in technology for the profession of pathology,” he added.

Gilbertson and other pathologists at MGH have worked with the Philips Intellisite Pathology Solution since 2011. “Before 2012, we had the system for a period of evaluation,” he said. “Then, starting in 2011 and 2012, we began using the system primarily for education, but also for clinical conferences.”

Today, Gilbertson’s lab needs additional scanning capacity. “We are oversubscribed with our current scanner in terms of education and clinical conferences,” he

noted. “The plan is to add more scanners just for those two applications. Of course, we regularly find more reasons to digitize the glass slides.”

MGH Pathologists were involved in some clinical trials that Philips ran as it pursued FDA approval. “There were a number of big studies that Philips did,” Gilbertson explained. “Several years ago, we worked with them on an immunohistochemistry study designed to demonstrate that use of digital images resulted in diagnoses comparable to those done from glass slides. We found the digital images to be comparable.

“Our pathology lab also did a pilot study with Philips to help design and power the pivotal study,” he said. “MGH was not involved in the pivotal study, which was the non-inferiority study. However, one of my colleagues, David Wilbur, MD, and I were on the advisory board. That’s how we know about it.” Wilbur is a pathologist at MGH and a Professor of Pathology at Harvard Medical School.

Another study in which MGH participated was a device-precision study. “This was to look at the reliability and consistency of the device itself,” stated Gilbertson. “For example, if a pathology lab were to use three devices to scan a single slide, would each device reproduce the same image? If two devices are in two different places, do you get the same image? That was a large study for us.”

This early experience with the digital pathology system and use of whole slide images at Partners Healthcare encouraged deployment of WSI to other locations within the healthcare system.

“During the time of the studies, we had as many as five scanners running to produce the images we needed for these studies,” he continued. “At the moment, we have only one scanner running. Our current plan is to purchase more, and we are in the process of doing that.”

TDR

—By Joseph Burns

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