

Is Digital Path Imaging Ready for Prime Time?

➤ **FDA clearance of digital pathology imaging is one factor that will encourage wider adoption**

➤➤ ***CEO SUMMARY: Digital pathology imaging systems are finding uses in all phases of drug discovery (discovery, pre-clinical, clinical trials), as well as education, research, and clinical. One hurdle to widespread adoption of fully digitized, whole-slide pathology imaging systems is FDA clearance that allows the use of this technology for primary diagnosis. Executives at two of companies offering digital pathology systems offer their predictions about how this market will evolve.***

IS DIGITAL PATHOLOGY ON THE VERGE OF BECOMING MAINSTREAM in the United States? Have advances in information technology (IT) and digital imaging reached the point where fast, detailed, and responsive systems can totally replace glass, paper, and microscopes in surgical pathology?

Several companies believe the answer will soon be yes. The newest entrant into digital pathology systems is **Omnyx, LLC**, (www.omnyxpath.com), the new \$40 million joint venture between **GE Healthcare** and the **University of Pittsburgh Medical Center** (UPMC). Omnyx intends to develop and market digital pathology systems for primary diagnosis. It believes it can have its products cleared by the FDA and into the pathology marketplace within two years. Omnyx promises that its system will perform whole-slide scanning in 30 seconds. (*See TDR, June 16, 2008.*)

To help pathologists and their practice administrators understand how fast things are changing in the field of digital pathology, **THE DARK REPORT** tracked down executives from **Aperio Technologies, Inc.**, and **DMetrix Inc.**—two companies currently selling digital

pathology systems in the United States and other countries around the world. Both are optimistic that digital technology is ready for day-to-day use in pathology groups and that market acceptance of digital pathology imaging is growing steadily.

➤ **GE's Entry Into Pathology**

“When a big company like GE enters the market, that’s good for everyone in our space, including Aperio,” commented Dirk G. Soenksen, CEO of Aperio Technologies, in Vista, California (www.aperio.com). “Undoubtedly that means there will be a lot of new competitors coming into the market. GE won’t be the last one. **Philips** is actively looking to participate in this market, and within the next two years, all the digital radiology companies will likely be focused on pathology as well.

“In fact, we encourage all those companies to learn more about digital pathology, just as GE did over the last few years,” Soenksen said. “GE visited us last year and we both shared our assessments about this market. They were evaluating several strategies for entering the digital pathology market and decided to partner with UPMC.”

Michael R. Descour, Ph.D., President of DMetrix Inc., in Tucson, Arizona, (www.dmetrix.com) agrees that GE's decision to enter the digital pathology market is a positive development. "The fact that GE is now involved in this market is stimulating interest from potential investors who want to go after companies that have innovative technology," Descour said. "Certainly there has also been a significant uptick in inquiries from potential customers who view the entry of GE as validation of this field."

"When GE puts down specific targets about the size of the market, the performance of instruments, and some real resources behind this effort," noted Descour, "then that has an immediate short-term effect that benefits companies like ours. We believe that GE's public entrance into digital pathology will directly help companies like ours over the next two years. This news gives us a significant opportunity in the coming months to grow the market for digital imaging systems in pathology."

► Challenges Ahead

Both Aperio and DMetrix acknowledged that other companies, such as **Carl Zeiss Inc.**, **Olympus**, **Nikon**, and **BioImagene, Inc.**, are developing digital pathology products for pathologists.

"One technical challenge for any slide scanner involves developing a system capable of focusing down to a fraction of a micron," Soenksen explained. "By comparison, the width of a human hair is 100 microns. Once the technology for generating well-focused high-quality digital slide images is perfected, FDA clearance must be obtained to market digital pathology systems for routine diagnostic review, in the same manner that pathologists routinely use microscopes and glass slides to make diagnoses. Right now, digital pathology systems are not cleared for use in the U.S. for the primary diagnosis of H&E specimens, although Aperio has obtained FDA clearance for manually reading (i.e.,

primary diagnosis of) digital HER2 slides on a computer monitor.

"But the market is poised to grow rapidly, almost the way radiology adopted digital imaging," commented Soenksen. "It took radiology 10 to 15 years to get to where it is today, and digital imaging in radiology is a very large market. Modality sales that include MRIs, CT, PET, CAT scanners and so forth represent up to \$9 billion per year. Sales of picture archiving and communication systems (PACS) represent another \$1.5 billion per year."

► Improving Workflow

"There is a fundamental difference, however, that sets radiology apart from pathology," continued Soenksen. "Radiology has fully adopted the use of digital imaging. By contrast, pathology is just beginning its evolution toward wider use of digital pathology systems and digital technologies."

"Pathology is adopting digital imaging in pieces, meaning customers use digital imaging technology for applications in specific niches," he added. "The idea that a hospital will digitize 100% of the glass slides in its system and that pathologists will read them out on a computer monitor in conjunction with an electronic medical record system is well into the future."

"It is GE's goal to develop a system for full adoption, and that highlights the difference between GE and Aperio," Soenksen explained. "Our strategy is to focus on where there is pain today by addressing the specific market needs of pathology customers. In fact, we believe there is no compelling reason today to routinely read digital slides on a computer monitor when the glass slide, the microscope, and the pathologist are all in the same room. In this case, reading glass slides will be more efficient. The value of digital pathology emerges for remote viewing applications where the glass slide is not co-located with the right pathologists, or for archival and retrieval, image analysis, or data management."

“Our customers include pathology groups of all sizes and none of them are digitizing 100% of the glass slides that they generate,” Soenksen said. “They take only a subset of those slides and digitize them, such as cases diagnosed with cancer or slides for tumor boards. Some pathology groups are instituting digital pathology systems to serve a remote hospital, for instance, obviating the need to ship glass slides or pathologists between facilities. Others use this technology for FDA-cleared applications, such as image analysis for Her-2 immunohistochemistry.

“There are several reasons why full adoption of digital pathology will take some time,” Soenksen added. “First, there are the technical challenges involved in simply engineering a solution to the throughput, workflow, and IT integration challenges. For example, how do you scan glass slides in a cost-effective way? How do you integrate the scanning systems into the existing workflow of surgical pathologists? And, finally, how do you integrate all of this new pathology information with an LIS or HIS? The bigger companies in healthcare informatics are not ready and waiting to solve this problem for pathologists.

“Second, there is a lack of publications and other proof sources that focus on the benefits and value of digital pathology, and draw attention to those groups successfully using digital pathology to address current challenges,” noted Soenksen. “It is difficult for pathologists to get credible information about the value of this technology.

► Improving Workflow

“Third, and perhaps most important in the United States, is that manufacturers of digital pathology systems cannot promote the use of digital pathology for making diagnoses from digital slide images of specimens displayed on a computer monitor,” observed Soenksen. “We have to demonstrate to the FDA that, what a pathologist sees on the digital slide image on a computer monitor and what the pathologist sees on the correspon-

Advice When Looking to Buy Digitized Pathology Systems

WHEN NEW TECHNOLOGY comes to market, it can be difficult for pathologists and lab directors to know how to invest in emerging systems. Both Dirk G. Soenksen, CEO of Aperio Technologies, Inc., in Vista, California, and Michael R. Descour, Ph.D., President of DMetrix Inc., in Tucson, Arizona, offered similar advice on this topic.

Point 1: Invest in an “open standards” system. If it turns out, a few years later, that the product is not a market leader, at least your lab will be able to use those digital images—produced by an open standards platform—in any new system.

Point 2: Invest in hardware and software that will be easy to upgrade. That makes it easier to acquire new imaging features. Leasing is a good option for maximizing upgrade opportunities.

Point 3: Test prospective digital systems before purchase to see how each performs in your laboratory environment. Vendors use the term “throughput,” but you won’t really know how it works unless you see it in your own laboratory.

ding glass slide through a microscope, yield the same diagnosis.

“This is a huge regulatory hurdle that is related to the most important performance parameter in this market, which is image quality. Image quality is critical in proving that what you see in a digital slide image is the same as what you see on a glass slide,” he continued. “For that reason, image quality cannot be compromised because then you will never overcome the regulatory hurdles.

“Aperio has FDA clearance for primary diagnosis of digital Her-2 immunohistochemistry slides,” stated Soenksen. “We demonstrated to the FDA that, if a pathologist reads an immunohistochemistry slide for Her-2 on a monitor, that pathologist will get an equivalent diagnosis as if he/she read the corresponding glass slide under a microscope.

“Once the FDA cleared our digital pathology system for IHC in 2007, we embarked on the process of obtaining FDA approval for reading digital H&E

slides on a computer monitor,” commented Soenksen. “We hope that FDA clearance of digital pathology for selected H&E applications will come in the second half of 2009. That will be an inflection point for the market because it will alleviate the potential concerns that digital pathology cannot support the accuracy required for making primary diagnosis from a computer monitor.”

► Considering Full Adoption

Descour also agreed that FDA clearance is a significant challenge. He further noted that many pathologists remain skeptical about imaging. “GE estimates that digital pathology imaging systems will be used to view some 1.5 billion tissue specimens worldwide per year,” Descour said. “Obviously, it will take some time before the market reaches that size.

“It’s not the size of the market for digitized pathology imaging that is in doubt, but the time to reach that size that is the uncertain parameter,” he added. “It’s uncertain because pathology customers will be switching away from the tried-and-true method of the glass slide and light microscope and adopting something new.

“The areas of pathology where adoption of digital imaging is growing fastest are research, pre-clinical use, and education,” observed Descour. “Adoption of digital pathology systems in healthcare is happening at places like UPMC, **M.D. Anderson**, the **Cleveland Clinic**, and **Massachusetts General Hospital**. These facilities are seriously studying how to deploy this technology to most effectively improve clinical performance.

“There are several reasons why wider adoption of digital imaging in pathology should increase in the coming years,” Descour explained. “First, digital imaging in radiology is well established and provides a template that we can follow for digital imaging in pathology. There are substantial differences of course, but there also are similarities. We at least have a

model and there are efforts, for example, to extend the DICOM standard for picture archiving and communication in medicine to digital pathology. There is also an ongoing effort to draft DICOM specifications for exchanging pathology images.

“Second, today—compared to a decade ago—most pathologists are much more familiar with computer and imaging technology and the lab and software interfaces that are needed to make digital imaging work in pathology,” he noted. “Young pathologists now coming out of training do not see digital pathology as something distinct from their everyday experience. The pervasiveness of this technology in medical education means we are primed to use this technology in clinical practice.”

DMetrix has some 30 patents for its systems and says it offers the world’s fastest slide scanners available today. Its systems use an array-microscope technology that allowed it to break the 60-second slide scan-time barrier in 2004.

► Considering Full Adoption

The Dark REPORT observes that digital imaging systems in pathology are poised to usher in a new generation of technology for pathologists and lab directors. Fortunately, pathologists have a model to follow. In the early 1990s, radiologists began adopting digital imaging systems for diagnosis. In the intervening years, the market grew significantly.

In the coming months and years, similar growth is likely to occur in pathology. Large companies will be choosing partners and developing systems for sale to pathologists in hospitals and labs of all sizes. The next step in the development of his nascent field is FDA approval. When that happens, it could mark the final days for the era of glass slides standard microscopes in pathology laboratories. **TDR**

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