# Newsbytes

## Digital pathology RFPs: from the questions to selections

February 2019—To those who request the information and those who supply the information, requests for proposal, better known as RFPs, can be groanworthy. Yet laboratories planning to purchase a digital pathology system for clinical use should seriously consider going through the painstaking process, even if their institutions don't require it, says Liron Pantanowitz, MD, vice chair of pathology informatics at the University of Pittsburgh Medical Center.

"If you want to buy a research or education tool, or something just to get your feet wet with a digital system, you don't really need an RFP," he says. "But once you bring in a system for clinical use, it's different. The standards are higher in terms of the IT requirements, and you want the system to be up all the time. So you need to step up your game in selecting it and make sure it's right for your lab."

In a presentation at the Association for Pathology Informatics' December API Digital Pathology and AI Workshop II and in a conversation with CAP TODAY, Dr. Pantanowitz described why and how digital pathology RFPs are worthwhile.

In selecting a new digital pathology system for UPMC, Dr. Pantanowitz and his colleagues developed an RFP using a structured method that is modeled on an RFP for lab information systems. However, he points out that choosing a digital pathology system poses unique challenges. "Most times, when people are selecting an LIS, they're evaluating the software. With digital pathology, there's a combination of hardware and software and that becomes confusing. Do you pick one system with the risk of getting locked into that vendor only, or should you mix and match?"

None of the end-to-end digital pathology solutions available will satisfy all the needs of every lab, Dr. Pantanowitz maintains. Therefore, labs need to determine how they plan to use the system before they create an RFP. "Some systems are good at frozen sections; others are better at image analysis," he explains. "Some, but not all, do fluorescence. Some are better than others if you want to do teaching work." Labs also need to take into consideration whether they use plastic coverslips or prepare whole mount slides and whether they provide consults on foreign slides with unique barcodes.

While it may be obvious, it's worth stating that labs need to determine, too, which digital pathology systems are compatible with their IT infrastructure. And "you need to ask, Will I just scan a few slides a day or is this high-volume work in a histology lab?" Dr. Pantanowitz says. Once all of the requirements are defined, "sit down with your chairman or your CIO and say, for example, 'We would like a clinical system that can do this, plus do image analysis, plus do education'—and then you need to know how much you can spend. Those are the two questions: What do you want, and can you afford it?"

Because labs may come up with hundreds of questions that they want to ask vendors during the RFP process, Dr. Pantanowitz suggests organizing questions by such categories as application functionality, hardware and software requirements, vendor support and training, and infrastructure requirements. Some questions may take vendors by surprise, he notes, because not all companies are accustomed to addressing clinical needs. For example, "when a scanner's down, [a vendor] can take a day or two to get to the client to get it up and running. We couldn't function like that in a clinical lab. So you have to ask, 'When a scanner jams because it's got a crushed slide in it, or when you scan an image and it doesn't show up in your LIS, can you send a consultant out to fix things the same day?' That's a big deal."

Another key consideration is whether a system is based on open architecture. Because digital pathology is a new and quickly evolving field, "when you buy a new system it's very likely things will change. There will be new algorithms, new modules, maybe an add-on for molecular pathology," Dr. Pantanowitz says. "So you don't want to

be locked into a system where the vendor won't allow you to work with all these newer, exciting tools coming along, particularly within the field of computational pathology and artificial intelligence." The catch, he notes, is that the FDA requires vendors to lock down their systems as a prerequisite for approval, and many labs will feel more comfortable using an FDA-approved system in a clinical environment. The UPMC pathologists chose a system that was not yet FDA approved, "but we made sure that one or more of that vendor's scanners would be FDA approved at some point in time. It had to be on their roadmap."

Many pathologists become enamored of scanners, robotics, and other hardware when they evaluate digital systems, Dr. Pantanowitz says, "but to be honest, the software is more important for a system in clinical use. You need to be able to manage all your cases and your patients, not just your images. Ask the vendor, 'Do you have proper case management software? If not, what are your plans and what experience do you have in integrating with LISs—in particular, my LIS?'" Many vendors fall short in this area but may be able to recommend another vendor to provide middleware for case management only, he adds.

Once the choices have been narrowed down through the RFP process, look for issues that may be red flags or even deal-breakers, Dr. Pantanowitz says. For example, beware if a vendor promises features or functionality that will be available in the future, because the system may not be operating at its full capacity. Conversely, some vendors will offer more than a lab really needs—"bells and whistles like image analysis, algorithms, molecular tools, which you don't need for just everyday digital pathology. Make sure that the stuff you need from day one is available. Don't get distracted," he warns. For UPMC, deal-breakers during the selection process included vendors that sought consideration without completing the RFP, those that couldn't show how their product would integrate with UPMC's LIS, and those who didn't bring their products to the on-site demonstration. "We had a vendor who came with only a PowerPoint presentation and a video but not their hardware," says Dr. Pantanowitz. "That doesn't cut it."

Finally, consider the company's reputation, he advises. When vendors' clients shared that their scanners were unreliable or image quality was inadequate, Dr. Pantanowitz says, or "if I was given warnings not to go with a particular system, even if the vendor answered fantastically on the RFP, that too became a deal-breaker." *—Jan Bowers*

*For additional questions and discussion points pertinent to creating a digital pathology RFP, provided by Dr. Pantanowitz, go to* **www.captodayonline.com/digital-path-RFP**.

## Xifin launches precision medicine informatics platform

Xifin has unveiled VisualStrata, a precision medicine informatics platform that curates and visualizes diagnostic, clinical, and financial data to document patient care through diagnosis, treatment, and outcomes.

VisualStrata offers real-world data analytics to assist health care providers and researchers with treatment planning, precision medicine programs, and population health initiatives; health care quality reporting capabilities to help fulfill the evidentiary and compliance needs of payers and health care institutions; temporal record and case management to collate structured and unstructured data from disparate systems into a single source to enhance the functionality of EHRs; and care team collaboration via a dashboard that allows care team members to share patient data and collaborate on cases in real time and on demand.

"Built for the health care industry by bioinformaticists and leveraging Xifin's 20 years' expertise in working with health care big data, VisualStrata seamlessly integrates with most electronic medical record systems and electronic health record systems," according to a company press release. "It also integrates with Xifin's RPM 10 and LIS 5 solutions, as well as other products that collect patient clinical, diagnostic, and financial data."

*Xifin, 858-793-5700*

## Beckman Coulter introduces cloud-based middleware

Beckman Coulter has released its DxOne Workflow Manager cloud-based middleware, which is designed to help

low-volume laboratories deliver timely patient results.

By integrating DxOne into their critical functions, laboratories can standardize and automate workflows across Beckman's chemistry, immunoassay, and hematology platforms. The software allows technologists to manage samples by exception using autoverification and provides automatic reflex testing.

The middleware features an intuitive interface with an at-a-glance view of ordering information and patient demographics on one screen. Comments and flags alert users to required actions based on laboratory-defined criteria. A sample-status overview feature shows items that need attention. Patient-associated results are consolidated on one screen and organized in graphs and by historical data.

*Beckman Coulter, 800-526-3821*

## Qiagen acquires N-of-One

Qiagen has entered an agreement to purchase N-of-One, a molecular oncology decision-support company and provider of clinical interpretation services for complex genomic data.

Under the agreement, Qiagen plans to integrate N-of-One's MarkerMine somatic cancer database and Precision Insights and Rapid Insights reporting tools into its Qiagen Clinical Insight solution for next-generation sequencing analysis and interpretation. The MarkerMine database contains more than 125,000 anonymized patient samples and will expand Qiagen's genomics knowledge base. N-of-One's technology helps pathologists produce case-specific reports using molecular test data.

"N-of-One has made tremendous strides in molecular oncology decision support, and their combination with Qiagen's own pre-curated knowledge base of evidence will provide powerful new tools to expand our abilities to deliver patient-specific insights," said Jonathan Sheldon, senior vice president of Qiagen's bioinformatics business area, in a press release.

*Qiagen, 800-426-8157*

## ARUP Laboratories and Techcyte collaborate

ARUP Laboratories has partnered with Techcyte to develop and commercialize digital diagnostic solutions using artificial intelligence.

"The collaboration between ARUP and Techcyte will significantly accelerate the number of new test algorithms available to the lab diagnostics market," according to a press release from Techcyte. "ARUP's vast expertise and access to rare samples combined with Techcyte's data-pipeline and machine-learning experts will produce high-quality algorithms that can be developed quickly and then introduced into the market following thorough testing."

Techcyte's digital diagnostics platform applies sophisticated convolutional neural networks to deliver test results to doctors and patients. The platform supports a range of whole slide scanners and such tests as blood differential, cervical cytology, fine-needle aspiration, fecal ova and parasites, urinalysis, and bacteriology.

*Techcyte, 801-980-0414*

## HL7 announces new release of FHIR standard

Health Level Seven International has published release four of the HL7 Fast Healthcare Interoperability Resources, or FHIR, standard.

The most significant change with release four is that the base platform of the standard has passed a normative ballot and will be submitted to the American National Standards Institute as a normative standard. "This means that future changes should be backward compatible so applications that implement the normative sections of R4 no longer risk being nonconformant to the standard," according to a press release from HL7.

The portions of the standard that are normative with the latest release include the RESTful application programming interface, XML and JSON formats, and basic data types; terminology layer (code system and value set); conformance framework (structure definition and capability statement); and patient and observation resources.

HL7 plans to bring more sections of the standard to normative status in its next release.

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