# Newsbytes

## Editors: Raymond D. Aller, MD, & Dennis Winsten

## How observer studies can help labs assess technology solutions

Ocotber 2023—Health care technology companies, by and large, are eager to share product metrics—that is, standalone product performance—with potential pathology lab clients but less eager to share how those technologies may impact laboratory workflow and decision-making.

“In the long run, I don’t really care that much about standalone performance,” asserted Elizabeth Krupinski, PhD, professor and vice chair for research, Department of Radiology and Imaging Sciences, Emory University. Dr. Krupinski shared her insights on using observer studies to evaluate how technologies influence users’ perceptions and practices in a presentation at the Association for Pathology Informatics’ 2023 Pathology Informatics Summit and in an interview with CAP TODAY.

Any change in the technology a laboratorian is using fundamentally changes that person’s perception of the task they are performing, which, in turn, can affect workflow, says Dr. Krupinski, who is an experimental psychologist. That means, for example, the way you look at a glass slide through a microscope versus a slide on a digital display “changes everything,” she says, because the technologies themselves affect your eye-tracking or search patterns when examining the image.

### To assess how a particular technology may impact pathologists and the workflow of the laboratory, Dr. Krupinski, who regularly collaborates with the pathology department at Emory, recommends conducting an observer study before making a switch.

An observer study administered in a controlled environment can yield unique insights into the effects of the technology because it is conducted with a uniform set of data and conditions, she explains.

Dr. Krupinski

An observer study typically should be performed before beta testing a new technology, Dr. Krupinski says. This is because beta testing demonstrates how the technology will be used in the normal flow of operations, but it doesn’t shed as much light on how the technology affects decision-making and pathologists’ perceptions because the cases that pathologists encounter during beta testing have not been pre-vetted, she says.

By contrast, Dr. Krupinski carefully selects cases of varying degrees of difficulty for participants to evaluate during an observer study. She recommends having a panel of three pathologists review selected cases before beginning the study. If the panelists agree on the diagnoses, it helps establish the study’s test set of cases as a standard of truth, she says.

The type and variety of pathology cases selected for the study can impact the results, she notes. If the test set for an observer study of a new artificial intelligence-based decision support tool, for example, includes too many easy cases, the tool being evaluated will not seem impactful because the participants will be able to make the diagnoses just as easily on their own, she says. Selecting extremely difficult cases that are not representative of

what pathologists typically encounter can also produce biased results. Therefore, Dr. Krupinski aims for a mix of easy cases (approximately 10 percent), cases that are a medium degree of difficulty (approximately 50 percent), and cases that are more difficult (40 percent).

Dr. Krupinski usually selects about 50 cases for an observer study, and she typically requires that six observers participate to ensure the study benefits from a broad enough range of perspectives. Several academic studies have proposed methodologies for determining the appropriate sample size for observer studies, she adds. For example, an article in the *American Journal of Roentgenology* includes tables that show how the ratio of cases to observers impacts the accuracy of receiver operating characteristic study results (Obuchowski NA. 2000. doi.org/10.2214/ajr.175.3.1750603). Another article, in *Biochemia Medica*, not only provides formulas that can be used to calculate an appropriate observer study sample size but also lists websites that offer calculators for estimating sample size (Serdar CC, et al. 2021. doi.org/10.11613/BM.2021.010502).

Dr. Krupinski favors conducting counterbalanced observer studies, which she breaks into two sessions. When testing an AI tool, for example, half the participants in the first session evaluate pathology images using the tool and the other half evaluate them unaided. In the second session, held approximately three weeks later, the participant groups are brought back to use the evaluation method they did not use in the first session.

It takes only about an hour to complete each session, Dr. Krupinski says, because the responses required for the study are much less extensive than the information that a pathologist would need to provide when signing out a case.

## Maintaining uniform conditions for an observer study requires carefully controlling numerous factors that can impact results, Dr. Krupinski says.

For example, studies have shown that the accuracy and speed of decision-making decrease late in the day, when people tend to be fatigued. Therefore, both observer study sessions should be conducted at the same time, preferably earlier in the day.

It is also important to carefully control the physical environment where the study is conducted, including the ambient lighting; quality and type of computer monitor used, particularly in digital pathology; and noise levels in the room. “The key is to keep everything as consistent as possible across observers throughout your study,” Dr. Krupinski says.

Organizers of these studies must also consider how pathology cases will be presented to the observers, Dr. Krupinski says. Will observers see only pathology images, or will they also have access to the associated clinical histories? If they have access to clinical histories, will they see that information before or after they look at the images? “It changes whether they go in with a preset impression,” she adds.

The results of some of the observer studies conducted by Dr. Krupinski have also helped other medical departments at Emory decide whether a certain type of technology would be a good fit. For example, observers in a recent study found the AI technology they were evaluating for their department to be cumbersome because it required too many clicks to obtain useful information.

Results of observer studies of AI tools don’t always match vendors’ claims about the effectiveness of their products, Dr. Krupinski says. AI vendors often suggest that their products can help all physicians make more accurate medical decisions. “What we have found over the years, in a lot of studies, is that is not always the case.”

Instead, AI tools often improve accuracy among residents and less experienced physicians, while the gains in accuracy for more experienced physicians are small. For that reason, Dr. Krupinski typically selects a mix of highly experienced pathologists and novices to serve as observers in studies, thereby allowing the studies to measure the effects of technology on different ability levels.

While AI tools for decision support may not greatly impact an experienced pathologist’s level of accuracy, she says,

they often have a more significant effect on the amount of time it takes to make decisions.

“Efficiency sometimes outweighs any gains in efficacy and accuracy because you’ll get less fatigued,” Dr. Krupinski explains. “You’ll be able to read more images in a given period of time, and you won’t have to be doing some of these mundane tasks, like counting nuclei, that can be done by something else, such as AI, far more efficiently.”

This speaks to the importance of identifying multiple goals when evaluating new technology, she continues. If improvements in accuracy are minimal, perhaps there are other metrics that make the technology investment worthwhile.

“I always, always measure how long it takes to interpret the images,” Dr. Krupinski says. “Maybe efficiency is going to be where the return on investment is.”

*—Renee Caruthers*

## ONC extends relationship with Sequoia Project

The Office of the National Coordinator for Health Information Technology has announced that the nonprofit Sequoia Project, a public-private collaborative that advocates for health care information technology interoperability and health information exchange, will continue as the recognized coordinating entity for the Trusted Exchange Framework and Common Agreement, or TEFCA.

The Sequoia Project has been awarded a five-year contract to continue public-private engagement in support of a nationwide framework for secure electronic health data sharing. It was selected as the recognized coordinating entity for TEFCA in 2019.

The organization hosts a recognized coordinating entity public information call on the third Tuesday of each month and posts recordings of calls and materials from stakeholder events on its website, rce.sequoiaproject.org.

The Sequoia Project will hold its 2023 annual meeting from Nov. 15 to 17, in San Diego.

## LigoLab introduces tiered pricing model for LIS

LigoLab Information Systems is now offering its laboratory information system, LigoLab Informatics Platform, via a tiered pricing structure to cater to various laboratory disciplines, sizes, and complexities.

Independent pathology groups and molecular and reference laboratories will be able to select the LIS platform tier that best aligns with their operations. The four pricing-based tiers address varying levels of need, said LigoLab CEO Suren Avunjian, in a company press release. “This means our lab partners not only have the features and capabilities to match their current needs but are also provided with a clear roadmap for future growth and development.”

The tiers include:

- essential, which provides an easy-to-use and straightforward LIS designed to meet the basic needs of small pathology, molecular, and reference laboratories.
- professional, which offers all the modules and features included in the essential tier plus more advanced reporting and analytics, enhanced workflow management, capabilities for integrating with other health care systems, and more complex order

management.

- advanced, which is designed to meet the needs of large, high-volume laboratories and labs with multiple locations. It incorporates all of the features of the essential and professional tiers and offers such tools as customer service modules, complex automation workflows, detailed analytics, business intelligence, advanced interoperability, inventory and supply management, and priority support.
- enterprise, which offers regional and national laboratories total integration across multiple departments and sites and broad scalability and highly customizable workflows. It includes all the features of the other tiers, as well as comprehensive enterprisewide capabilities, such as premium customer support services and advanced data governance.

*LigoLab, 800-544-6522*

## Data Innovations offers upgrade to cloud-hosted SaaS product

Data Innovations has released Lab GPS, version 2.0, which addresses unplanned laboratory downtime due to connectivity, power, and hardware issues, for the company's Instrument Manager connectivity and automation platform clients in the United States.

This latest version, a major upgrade to Data Innovations' first software-as-a-service product, allows laboratories to monitor lab information system and instrument connections across multiple locations from a single dashboard. It also provides automated email notifications of downed Instrument Manager, LIS, and instrument connections; remote connection restart capability; and troubleshooting tools for information technology administrators.

"Lab GPS v2.0 offers a robust alert and notification system that allows users to choose when they would like specific connections to be monitored and who should receive email notifications," according to a company press release.

Medical facility staff with the appropriate security clearance can stop and start connections using any device that has Web access.

*Data Innovations, 866-271-9094*

## Tribun Health secures Series B funding

The Paris-based digital pathology company Tribun Health has completed its Series B financing round, securing the equivalent of approximately $16 million (U.S. dollars) from several investors.

The Series B funding further strengthens the company's financial position and opens new opportunities for growth in Europe and North America.

Tribun Health will use the infusion of capital, in part, to accelerate the development and commercialization of its

artificial intelligence-powered digital pathology platform for analyzing and interpreting histological and cytological samples and expanding its sales and marketing activities in Europe and North America.

## Talkdesk joins Epic Pals program

Talkdesk, a global provider of artificial intelligence-powered cloud-based contact centers for enterprises of all sizes, has joined Epic's Pals program, under which it will integrate its Talkdesk Healthcare Experience Cloud platform with Epic's EHR software.

Talkdesk is the first contact-center-as-a-service vendor to become a member of the new Pals program, which is intended to help Epic's clients select vendors that have "validated integrations" with Epic's software, according to a press release from Talkdesk.

The companies plan to co-innovate to offer their mutual customers new solutions, including advanced voice and digital contact center capabilities from Talkdesk integrated with current and future features of Epic's Cheers customer-relationship–management product suite.

In August, the company Abridge, a developer of generative AI tools for clinical documentation, became the first vendor to join Epic's Pals program.

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