# Newsbytes

## The nitty-gritty of TLA system requests for proposal

Feburary 2021—Laboratories involved in requests for proposal for total lab automation systems may want to consider the words of wisdom of Francis of Assisi: “For it is in giving that we receive.”

Or, as Jonathan Genzen, MD, PhD, put it: In an RFP, information flows both ways, so establishing what data to share with a vendor can be as critical to the process as understanding what information to request. Dr. Genzen, chief operating officer at ARUP Laboratories, Salt Lake City, has spoken about undertaking an RFP process for a total laboratory automation system at American Association for Clinical Chemistry and other health care industry meetings and, more recently, in a conversation with CAP TODAY. (See Dr. Genzen’s tips on determining whether to automate and how to assess TLA needs in last month’s “Newsbytes” column.)

The RFP process is the laboratory’s opportunity to request detailed equipment implementation plans, service plans, reagent assay specifications, and expected test turnaround times and to determine if vendors can meet the lab’s electrical, water, and drainage requirements and constraints, all based on the information the lab has provided to those vendors, Dr. Genzen says. To provide the most accurate proposal possible, vendors need such information as laboratory dimensions so they can create diagrams illustrating possible equipment configurations and detailed analyses of how much space a piece of equipment will require. “Just because an instrument is two-foot-by-three-foot doesn’t mean that’s the space it requires. It may need even more space for service and operation,” he says.

Dr. Genzen

Vendors may also need detailed laboratory data extracts to estimate the number of centrifuges, decappers, and other instrumentation the laboratory will require for its automation system. “There is a lot of information in that type of data, and some of it may not be necessary to answer the questions that a vendor is trying to respond to,” Dr. Genzen notes. Therefore, it is critically important that laboratories de-identify information that is requested as part of the RFP process. Nondisclosure agreements and business associate agreements can help ensure that information is handled properly, he adds.

Laboratories should also use caution if vendors request data that exceed what is reasonably necessary, Dr. Genzen says. This may suggest that a company is looking for business opportunities beyond the scope of the RFP. “Many vendors have multiple business arms related to different disciplines,” he explains, so if vendors seek information outside the scope of the project, the lab should further discuss the requests with them. “Those boundaries need to be respected.”

Once information-sharing guidelines are established, laboratory decision-makers can feel confident collaborating and seeking a variety of information related to the automation project, such as requesting comprehensive information about all of the assays being proposed for automation. The latter includes instrument package inserts that contain technical information and analytical performance details. Instruments and assays from different companies have different performance specifications, Dr. Genzen says, which can impact “IT builds, reference ranges, and even how frequently you need to repeat specimens with dilutions that may be outside the analytical measurement range.”

Companies present assay performance specifications in different ways, and even highly technical information in

package inserts may not provide all of the needed answers, Dr. Genzen continues. “What is interesting to me,” he says, “is that not all vendors will specifically state what an acceptable performance level is. The package insert will say how it performed in studies submitted to the FDA, but that’s different conceptually than having a predefined functional threshold of ‘this is acceptable, this is not acceptable.’ The lab should ask if a vendor has tables of acceptability limits used by their own application specialists or that may be available in other sources.”

As laboratories acquire information from vendors, they should “maintain a critical eye” as it’s natural to idealize or present information in the most optimal light, Dr. Genzen says. He cites as an example test turnaround times. “You want the information that’s analyzed to be reflective of your entire test menu and operational patterns and not a subset of tests that happen to have a faster analytical turnaround time.”

The same level of caution should be applied to using RFPs for modeling future staffing needs. “It is reasonable during an RFP to ask a vendor to provide analyses related to staffing requirements for the instrumentation being proposed,” Dr. Genzen says. “A healthy dose of skepticism should certainly be applied when projections seem unrealistic. But lab tours of facilities currently using the proposed automation can provide a reality check of what level of staffing is really required to operate the system.”

While site visits may not be possible during the pandemic, they typically are a crucial part of the vendor-selection process because they allow labs to see firsthand aspects of running the proposed equipment that can’t be conveyed through written documents provided as part of an RFP, according to Dr. Genzen. For this reason, it is important to work with potential vendors to schedule site visits with labs of similar size and complexity, he notes.

“When you go to these site visits, it’s not just looking at the system and its configuration, it’s also keeping an eye on how many operators are standing along the automation system or the instruments,” Dr. Genzen says. “What are they doing? Is it one or two people running a fully automated system that is doing everything you would expect the track to do? Or is it a dozen people working on instruments with track components in various stages of availability?”

Lab teams should also pay attention to track warning lights and the noise level in the workplace during their site visits, he says. Furthermore, they should ask the instrument operators how frequently they load reagents and how much downtime the equipment requires, as well as solicit pros and cons about their experience with the system and the installation process. “This type of real-world information is incredibly valuable,” he adds.

Dr. Genzen advises setting aside some time during a site visit to observe and interact with staff at the host site without the vendor present or, at a minimum, holding a private conversation with some members of the lab team at the host site during or after the visit. “People speak more openly when it’s peer to peer,” he says. “I think that’s really important. And most vendors recognize the importance of this type of information sharing as well. Such conversations can be particularly helpful when discussing a vendor’s level of assistance with service, assay reliability, and recalls, and overall responsiveness.”

Laboratory decision-makers should also inquire about the funding of site visits. Some labs may not have a budget for such visits and, therefore, may depend on vendors to provide financial support for these trips, Dr. Genzen says, while others may be limited by institutional restrictions on vendor-sponsored activities. “This needs to be clarified in advance to avoid the potential for perceived influence on purchasing decisions.”

To justify the need for a potential site visit, or if site visits are not possible, Dr. Genzen suggests calling multiple labs that have installed the equipment under consideration. “We do ask vendors for contact information for multiple sites using instruments under consideration so we can independently chat with those sites and make sure that we have the opportunity to really talk about what has worked and what hasn’t worked well,” he says. “You learn a lot from that dynamic and build professional connections. [And] these sites may also have questions for you.”

Just as labs should look to their counterparts for guidance with automation system RFPs, they should look inward to their own hospital departments for assistance, Dr. Genzen says. The purchasing and information technology

departments, in particular, can help in "understanding the specifics that might not jump off the page to the laboratory but might be a real headache down the road." Having someone from the purchasing team involved in contract negotiations is critical, he explains. They can analyze the pricing for different types of service models based on numerous factors, such as contract length, to determine the most cost-effective plan for the laboratory. "A shorter contract may cost more per year, and a longer contract may be committing you to reagent pricing for a longer span of time, which can be good or bad," he says. "Favorable pricing can be good because it locks in pricing, but if your test volumes change, it can get a little rough." Dr. Genzen also advises obtaining an example of a vendor's boilerplate contract for large-scale automation because understanding a vendor's typical contractual terms can head off potential disputes later on.

Information technology staff also bring a specific skill set and related questions to the RFP process that may be outside the laboratory team's wheelhouse, particularly with regard to the complexity of middleware and the lab information system installation process. The lab should involve IT staff in the selection process sooner than later because "you want to avoid a circumstance where you launch a giant project and then you realize the IT team is already committed to other important priorities or projects and doesn't have availability at this time," Dr. Genzen says.

The RFP process can be lengthy and complicated, he adds, "but having good project management can help you identify and navigate challenges early on."

*—Renee Caruthers*

## OptumInsight to merge with Change Healthcare

UnitedHealth Group has announced plans to purchase Change Healthcare as part of a deal that would combine Change with UnitedHealth's OptumInsight business unit to expand Optum's health care industry software and services.

"Change Healthcare brings widely adopted technology for integrating evidence-based clinical criteria directly into the clinician's workflow, while Optum's clinical analytics expertise and individual health record can strengthen the evidence base needed to deliver effective clinical decision support at the point of care," according to a joint press release from the companies.

Change Healthcare's revenue cycle management and other financial solutions will also enhance Optum's automated payment network by simplifying financial interactions between care providers, payers, and health care consumers, the companies reported.

The deal is expected to close in the second half of this year.

*UnitedHealth Group, 888-445-8745*
*Change Healthcare, 866-817-3813*

## NovoPath receives leadership award from Frost & Sullivan

NovoPath has received the Frost & Sullivan 2021 Enabling Technology Leadership award in the North American laboratory information systems workflow solutions industry.

Companies nominated for the award were evaluated based on such criteria as commitment to innovation and creativity; commercialization success; price/performance value; application diversity; and customers' purchase, ownership, and service experience.

Frost & Sullivan recognized NovoPath for such practices as rapidly addressing customer inquiries and support needs; quickly responding to changes in the laboratory marketplace by tackling the demands of COVID-19; expanding its focus to emerging specialty testing markets, such as molecular diagnostics and digital pathology; and offering cloud-based and client-hosted solutions to meet laboratories' infrastructure and financial

requirements.

NovoPath markets software for anatomic, clinical, and molecular pathology and introduced its flagship NovoPath anatomic pathology system more than two decades ago. Frost & Sullivan is a business consulting and market research and analysis company.

*NovoPath, 877-668-6123*

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