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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Come One, Come All to the Executive War College

THIS IS FOR ALL OF YOU LONG-TIME READERS WHO EVERY SPRING SEE NEWS about the *Executive War College on Diagnostics, Laboratory, and Pathology Management*, tell yourself that you need to attend, but then you put off registering.

Your message today is simple and supported by compelling logic: this is the year for you to make time, register, travel to New Orleans, and spend two highly-productive days with more than 900 of the lab profession's most capable administrators, executives, and pathologists.

In more than 80 sessions, over 125 innovative and accomplished speakers and panelists will be on stage and sharing stories of their labs' successes with new management methods, new lab automation and tests, and effective approaches to working with payers to obtain reasonable reimbursement and gain network status. It is your opportunity to acquire the knowledge and confidence you need to address the common issues of lab staffing shortages, effective cost-cutting, and developing important new sources of revenue for your laboratory.

Each year, some clients and loyal readers do take the plunge, register, and show up for their first *Executive War College* experience. They will stop Editor-in-Chief, Robert L. Michel or other staff members and, with genuine enthusiasm, say this is the most valuable lab conference they've attended in years. This real testimonial captures that energy: "My first *EWC* was an amazing conference, and it taught me more in three days than my company had in two years!"

There is another compelling reason why this is the year for you and your key managers to get out of the lab and spend two days at the nation's biggest gathering of management-minded lab leaders. My diagnosis is that you are coming down from the high stress of the past 36 months of the pandemic, with its seven-day weeks and lockdowns. My prescription is that you and your most talented lab managers register today and travel together to the 28th annual *Executive War College* on April 25-26.

Yes! It is time for you to step away from that laboratory facility, travel to one of the nation's most fun cities with fabulous cuisine, and hang out with 900 or more of your peers—the cream of lab management who are pushing our profession forward in effective ways. You'll return to your lab refreshed and energized. Even better, you'll bring back proven ideas that advance the clinical and financial success of your lab. TDR

Six Important Themes to Help Labs Succeed

Upcoming *Executive War College* to address healthcare's changes and opportunities for labs

CEO SUMMARY: Clinical laboratories face business challenges with day-to-day operations, genetic testing, and evolving care delivery models. The 2023 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management returns on April 25-26 in New Orleans. Participants will learn what is changing in the healthcare and lab testing sectors, along with effective responses that can advance their lab testing services while generating welcome new sources of revenue.

RETURNING FOR ITS 28TH YEAR, the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* will focus on six pressing themes. These specific issues affect the ability of labs and pathology groups to survive and thrive during healthcare's transformation and as fee-for-service gives way to value-based reimbursement arrangements.

"Today, the U.S. healthcare system is transforming itself with unprecedented speed," declared Robert Michel, Editor-in-Chief of THE DARK REPORT and founder of the conference. "Big multi-hospital health systems are merging with each other. The new healthcare consumers want direct access to clinical laboratory tests and the full record of their lab test history. Payers are slashing reimbursement for many medical lab tests.

"These are three examples of major changes unfolding in the delivery and reimbursement of clinical services," he continued. "Each has major implications in how labs serve their parent organizations, offer services directly to consumers, and negotiate with payers for fair reimbursement as in-network providers."

The *Executive War College* (EWC) takes place April 25-26 in New Orleans. An anticipated 125 speakers will present 80 sessions on a variety of issues that influence how labs run their businesses. Visit *www.ExecutiveWarCollege.com* for full details.

Briefings about the six lab-based themes to be featured at EWC are on pages 6-8 in this issue. The trends break down into a trio of overlapping areas:

- Day-to-day operations in the clinical laboratory or pathology practice.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Diagnostics Better Reflected at 2023 EWC Conference

Eagle-eyed readers might notice a name that looks slightly different: the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*.

"Dark Report subscribers and long-time attendees will notice that we tweaked the *Executive War College's* full title to emphasize 'diagnostics. That term is an important addition," noted Robert Michel, founder of the *EWC* conference. "In the past, 'clinical laboratory' and 'anatomic pathology' were terms that sufficiently described the profession of laboratory medicine. However, a subtle but significant change has occurred in recent years. The term 'diagnostics' has become a common description for medical testing, along with other diagnostic areas such as radiology and imaging."

- The growing world of genetic testing and related reimbursement.
- An evolution in how consumers expect to receive healthcare services and medical treatments.

"Each of these broad areas are on the radar of observant laboratory leaders," Michel noted. "In developing the *Executive War College's* agenda and inviting expert speakers, it is clear that many laboratories will struggle in one or more of these areas this year."

Future of LDT Regulation

Within the theme involving day-to-day operation of labs, the uncertain regulatory landscape will get full attention at *Executive War College*. Major regulatory changes are expected in the coming 24 months. Expert speakers will address two hot spots: the potential of increased regulation of laboratory-developed tests (LDTs) and planned reforms to the Clinical Laboratory Improvement Amendments (CLIA) of 1988. *(See the briefing on page 6 for more information.)*

"There may be revisions to two significant laws that would affect just about every laboratory in the United States," Michel said. "One of those developments involves the FDA's efforts to regulate LDTs. The other is a quieter, ongoing project to identify and implement updates to CLIA regulations. Together, each of these developments has a potentially transformative impact on labs."

Multiple sessions at the *Executive War College* will assess these developments. "There will be panels on the legal and federal government's aspects of LDT regulation involving multiple experts," Michel said.

"Additionally, the *Executive War College* has invited Reynolds Salerno, PhD, Director of the **Centers for Disease Control and Prevention's Division of Laboratory Systems**, to talk about activities that are underway to propose substantial revisions to CLIA, which has undergone little change in the past 30 years," he added.

Aspects of Hiring

Another aspect of day-to-day operations to be addressed is the recruiting, hiring, and retention of medical laboratory scientists and anatomic pathologists. *(See the briefing on page 6.)*

The lab staffing shortage has been well chronicled in these pages. However, this year's *Executive War College* will feature a new emphasis on up-to-minute perspectives about supply and demand for laboratory scientists and pathologists.

"Among sessions devoted to this topic is a presentation about current developments in the placements of medical technologists, histotechs, cytotechs, and other lab scientists," Michel explained. "Attendees will gain insights as to how to attract qualified candidates, along with reports on the current level of salaries and benefits for these positions.

"Another significant theme that is different at the upcoming conference versus earlier years is the increasingly rapid uptake of genetic testing and genome sequencing by local labs and health system laboratories," Michel said.

Genetic testing, and the struggle to have claims reimbursed, will be an important topic this year. In what may be a lab industry first, attendees at the *Executive War College* will hear about **Optum's** laboratory benefit management program that it is offering to other health plans and self-insured employers.

This session will be jointly presented by Cristi Radford, MS, CGC, Product Director, at Optum, and Jason Bush, PhD, Executive Vice President, Product, at **Avalon Healthcare Solutions**. *(See the briefing on page 7.)*

Must-Attend Session

"This is a must-attend session for any lab manager wanting to understand how one of the nation's largest payers views the explosion in genetic testing—along with the tsunami of genetic test claims that overwhelms health plans," Michel observed. "This is a rare opportunity for lab managers and pathologists to hear from individuals who sit on the payer side of the managed care table."

Other sessions at the conference will be devoted to discussing how community hospitals and local labs can set up and offer genetic tests and next-gen sequencing services. There will be a one-day, post-conference workshop on the topic. During these sessions, attendees will learn about the new phenomenon in the lab marketplace of "dry labs" and "virtual CLIA labs"—organizations that take genetic data generated by a "wet lab" and process that data, annotate it, and provide an analysis and interpretation for the referring physician.

Consumers' preference in where they receive healthcare and the services they expect from providers continues to evolve.

Prominent Themes at Executive War College

HERE'S A QUICK RUNDOWN of six themes that the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* will showcase:

1. Clinical laboratories head into an unstable regulatory environment.
2. Solutions to chronic lab staffing shortage evolve as demand rises.
3. Laboratories face challenges to navigate the genetic testing landscape.
4. Prior-authorization mandates stymie labs performing expensive tests.
5. Changes continue in how primary care is delivered to consumers.
6. New lab opportunities in precision medicine and proactive care.

For more details on each theme, see the briefings on pages 6-8.

Patients increasingly seek out primary care services, including routine diagnostic tests, at retail pharmacies. Another aspect is how demand for precision medicine is driving consumer behavior. *(See the briefings on page 8.)*

"Labs need to go beyond providing an accurate, timely test result to also delivering actionable intelligence to providers that directly improves care, such as through diagnostic data and precision medicine," Michel observed.

Among the presenters who will address this topic will be William Morice II, MD, PhD, CEO and President at **Mayo Clinic Laboratories**. Morice will offer ways for labs to rethink their role in supporting precision medicine.

"*Executive War College* serves strategic thinkers in clinical laboratories," Michel concluded. "Presenters will explore ways lab innovators can stay on the front lines of clinical quality while also operating in a financially responsible way." TDR

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Executive War College

TREND 1

Significant Federal Regulatory Reforms Progressing with FDA, CLIA Regulations

DURING THE COMING 12 TO 36 MONTHS there are reasons to expect several seismic events in the regulation of clinical labs.

Lab managers and pathologists should monitor activity in the nation's capital among **Congress**, rulemaking agencies, healthcare officials, and lobbyists. Two areas are of particular note: oversight of laboratory-developed tests (LDTs) and proposed reforms to the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

There were reasons to expect LDT oversight to move to the **Food and Drug Administration** (FDA) last year. However, proposed legislation to do so was kept off a spending bill in Congress, partly because of strong opposition from academic medical center pathologists.

Now, the FDA indicates it will file its own rulemaking to govern laboratory-developed tests. At the same time, it is plausible that another LDT bill may surface in Congress during 2023.

Meanwhile, THE DARK REPORT has outlined recommended reforms to CLIA. Many of them focus on how revisions to the statute should address diagnostic data, people who handle this data, and related technology such as digital pathology. These CLIA changes won't happen in 2023, but they will be considered by federal officials later this year.

*Related **Executive War College** session: "Everything You Need to Know about Washington, DC: Issues of Concern to Labs, including PAMA, VALID Act, FDA, OIG, CMS, Congress, and More."*

Executive War College

TREND 2

Chronic Lab Staffing Shortages Remain Even as Demand Rises

IT REMAINS A STRUGGLE FOR MOST LABS TO ATTRACT, HIRE, AND RETAIN QUALIFIED PERSONNEL across all skill positions. From medical technologists (MTs) to phlebotomists and accessioners, demand far outstrips supply.

Compounding the lack of adequate numbers of trained and experienced lab workers is the steady rise in wages. Candidates want more money, and inflation only exacerbates that issue.

In this tight labor market, clinical laboratories must do two things. First, differentiate their organizations and corporate cultures in ways that appeal to top-performing lab professionals.

Second, labs must be creative in how they go about recruiting, hiring, and retaining qualified workers. Sure, competitive wages are a must. But in this fierce market it is essential that labs promote their open positions in ways that catch the attention of qualified candidates and encourage them to arrange a hiring interview.

Such novel thinking is a must in a competitive talent market. Our story on page 9 about how **ARUP Laboratories** secured federal funding for a new clinical laboratory scientist training center is a prime example of an unconventional approach to expanding the supply of qualified medical technologists.

*Related **Executive War College** session: "Lab Staff Recruiting, Hiring, and Retention in Today's Competitive Market: How We Differentiate Our Lab, Attract Qualified Candidates, and Build Loyalty and Commitment."*

Executive War College

TREND 3

Laboratories Face Big Challenges Navigating Genetic Test Landscape

"Overwhelming" may be the best way to describe the genetic testing world from the perspective of laboratory professionals. **Concert Genetics** tracks 175,000 genetic tests offered today to providers.

The current marketplace for genetic tests can be a morass. On one hand, more patients want access to genetic tests they believe are relevant to their medical care. On the other hand, health insurers are overwhelmed by genetic test claims. Their response is to require prior-authorization requirements and deny coverage to new genetic tests that lack adequate data to support accuracy and clinical relevance.

The demand for genetic testing among providers and the public is strong, particularly for personalized medicine use. Meanwhile, with the SARS-CoV-2 federal public health emergency set to expire on May 11 and demand for COVID-19 testing down significantly from a year ago, those hospital and independent labs that devoted PCR resources to molecular SARS-CoV-2 testing now have the opportunity to repurpose their COVID equipment and add staff to perform genetic testing.

In the face of eroding hospital finances, genetic testing could boost lab revenue. But that takes strategic planning and careful collaboration with payers to get reimbursed. All of these issues will be discussed at the *Executive War College*.

*Related **Executive War College** full-day workshop: "Genetic Testing and Genome Sequencing for Community Hospital Labs."*

Executive War College

TREND 4

Payers' Prior-Authorization Mandates Stymie Labs Performing Expensive Tests

One consequence of the sharp rise in genetic testing over the past decade is that private payers struggle with huge numbers of claims for novel assays, some of which have questionable clinical value.

To combat this problem, two of the biggest private payers, **UnitedHealthcare** and **Anthem** (now known as **Elevance Health**), instituted prior authorization programs for genetic testing in 2017. Prior authorization is one aspect of laboratory benefit management (LBM) programs, so it was no surprise to see molecular tests fall under these setups.

Just last year, **Optum** (which is owned by UnitedHealthcare's parent, **UnitedHealth Group**) announced it was offering its LBM option to other insurers to improve use of expensive genetic tests.

For many genetic testing companies, Optum's move was likely not popular. When labs wait for authorization, they run the risk of delaying the test and irritating ordering physicians. For this reason, some labs instead choose to perform the test and absorb the costs to keep doctors happy. That is why working with LBM programs is a key step for genetic testing laboratories.

*Related **Executive War College** session: "Understanding Lab Benefit Management Programs: Why They Exist, What They Do, and the Benefits They Offer to Patients, Physicians, and Payers."*

Executive War College

TREND 5

Changes in Delivery of Primary Care Have Major Implications for Labs

IT MAY BE OFF THE RADAR SCREENS OF MANY LAB ADMINISTRATORS AND PATHOLOGISTS, but the transformation of primary care in this country is advancing at a steady pace. This trend has significant implications for clinical laboratories because it changes the locations where increasing numbers of patients will seek primary care.

Leading this charge are **Walgreens, Walmart**, **CVS**, and several grocery store chains. Consumers are clearly open to receiving physician care, clinical laboratory diagnostic tests, and follow-up treatments in non-traditional settings outside of hospitals and doctor offices.

This is happening because retail pharmacy chains are losing access to patients and being disintermediated by pharmacy benefit managers (PBMs) and Amazon's PillPack service. By establishing primary care services within retail pharmacies, not only do these companies establish a new source of revenue, but it also positions them to provide the prescriptions needed by these patients.

As an ancillary service that supports primary care providers, clinical laboratories must have a strategy to respond to this trend. Labs are faced with important logistical questions. Among them:

- How are diagnostic specimens collected?
- How do the specimens get to the lab?
- Are payers aware of the setup?

*Related **Executive War College** session: "Is It Time for Retail Pharmacies and Clinical Labs to Start a Dating Relationship to Offer Value to Each Other?"*

Executive War College

TREND 6

Clinical Labs Have New Opportunities in Precision Medicine, Proactive Care

WHEN PROPERLY CURATED AND ANALYZED, DIAGNOSTIC DATA can serve as a powerful tool for artificial intelligence (AI) and precision medicine.

With this data in hand, clinical laboratories and pathology groups can provide valuable information to specialists, clinical trial organizers, and others as they piece together individualized care plans for patients.

For example, the **University of Pittsburgh School of Medicine** has decided to include pathology data in a machine learning process that could help classify HIV test results as likely positive or likely negative based on patient populations. Infant HIV tests are predominantly negative, but community clinic HIV tests draw more positives, according to a story posted online in March by the **American Association for Clinical Chemistry**.

"This provides the laboratory with new opportunities to personalize workflows and provide clinicians and patients with the answers they need rather than just a number from our instruments," the article states.

*Related **Executive War College** session: "Rethinking the Lab's Role to Support Precision Medicine, Serve the New Consumer, and Create Value from Data to Support Improved Patient Care and Save on Cost of Care."*

Best Practices for Labs to Secure MT Program Funds

University of Utah and ARUP Labs share why they were successful securing $3M in federal funds

Tracy George, MD

CEO SUMMARY: In securing federal funds for a new MT training center, ARUP Labs and the University of Utah took steps that clinical labs can follow for their own project financing. Among the key lessons is the need to showcase the work a lab does within a community to politicians and decision-makers who control funding sources.

Diana Wilkins, PhD

PART TWO OF TWO PARTS

TO SECURE $3 MILLION IN FEDERAL FUNDING to build a new medical technologist (MT) training center, **ARUP Laboratories**, in partnership with the **University of Utah**, took a unique approach that other clinical laboratories can emulate.

"It's important that lab leaders explore novel ways to get funding [for med tech training programs]," said Tracy George, MD, President and Chief Scientific Officer at ARUP. "Our project was outside-the-box thinking."

Part one of our report about the novel source of funding for this new MT training center explains the data on staff shortages project organizers used in their request for federal funding and how they presented that data to lawmakers. *(See TDR, "ARUP, University of Utah Create MT Training Center," March 6, 2023.)*

Part two of this intelligence briefing explains how ARUP and the University of Utah—both in Salt Lake City—are using the federal funds to build the MT training center. Also included are recommendations as to how other labs can replicate this process to secure funding through the federal government and other sources.

The new facility is formally called the **Advanced Practice Clinical Laboratory Training Center**. Medical laboratory science students at the University of Utah will learn advanced clinical diagnostic testing techniques at the training center. They will then finish their education in more specialized testing environments at ARUP Laboratories or other lab locations.

Sharing New Learning

The immediate path forward for the project is to get the training center operational by 2024. Architectural plans are currently being drawn up. Once open, the facility will help the University of Utah's Division of Medical Laboratory Sciences to reach the goal of doubling to 80 the number of annual lab science undergraduates.

However, a more auspicious goal is to encourage other clinical laboratories to copy this model and launch their own medical technologist training programs in conjunction with their local colleges and universities.

"We are very committed to sharing what we learn in this experience," said Jonathan Genzen, MD, PhD, Chief Medical Officer at ARUP. "It is public funding. We are a nonprofit institution affiliated with the university. Everything about this project is designed to share that experience so that it can be replicated in other appropriate settings."

Supporting the Community

Helping the larger region around this MT training center is high on the wish list of Diana Wilkins, PhD, Chief of the Division of Medical Laboratory Sciences in the university's Department of Pathology.

Wilkins said she is particularly excited to someday expand training within the Intermountain West region of the country, in which Utah and nearby states are located. "I hope we find opportunities for areas across the Intermountain West that may have difficulty finding MT training sites for students," she added. "If University of Utah can help support and promote MT student training in the long term beyond just our local community—such as across the state and in the Intermountain region—that's a benefit to everybody in the region and to the economy."

Jonathan Genzen, MD, PhD

➤"It really makes a difference if your local representatives or congressional representatives know what your lab is doing."

Wilkins added that the medical laboratory sciences undergraduate program will have no trouble filling the 40 new training slots the MT center will open up.

"It's going to solve a critical need for us as an academic program because there are currently over 200 premedical laboratory sciences undergraduate students who are now freshman or sophomores at the University of Utah," she said. "During their junior and senior years, they want to advance into their clinical training. I want to move these students along so that they can enter the workforce and provide quality healthcare to our community.

"We don't want them to take six or seven years to graduate. We want them to complete their undergraduate degree in the more traditional timeframe for a university graduate and to be well prepared as a new workforce member to hit the ground running," she continued. "This training center is going to be a great opportunity for us to be able to achieve that goal."

Tips That Labs Can Emulate

The MT project's innovators provided interesting details about why they were successful at securing the federal funds.

They presented the following six recommendations that any clinical laboratory can use to pursue its own funding requests more successfully:

- **Publicly hitch the lab's work to a state's economic or academic goals**. "Utah is definitely focused on STEM education, technology innovation, and job creation in those areas," Genzen said. "ARUP's project aligned well with a lot of the priorities that we see in the Salt Lake City Valley and Utah state in general. That helped us tremendously."
- **Promote how a community can benefit from a clinical lab project**. Medical laboratories have the attention of the public and of lawmakers because of how vital diagnostic tests proved to be during the pandemic. Let the community know how future projects involving the lab will improve their lives. "It really makes a difference if your local representatives or congressional representatives know what your lab is doing, understand what's happening in those environments, and have a sense of what's needed to help expand efforts to make those lab testing services even better," Genzen noted.
- **Offer laboratory tours to local, state, and federal leaders**. Genzen joked that

ARUP never says no to a requested lab visit. "The purpose of these tours is to share the message about the great work the lab is doing and to share information about why a future lab project, like our training center, will be important," he said. "We already had connections with congressional representatives, largely because of our role during the COVID-19 pandemic. They knew of our laboratory and what we were trying to accomplish."

- **Gather letters of support from the community**. In the case of ARUP and the University of Utah, the federal funding program required the recipients to present letters of community support. "The letters we submitted gave lawmakers reassurance that other people in the community also believed in the project," Genzen explained.
- **Focus on Medical Laboratory Professionals Week**. This annual spring event, which this year occurs April 23-29, is a great opportunity to get political leaders involved with local labs. "Communicate with your local legislators about Medical Laboratory Professionals Week," Wilkins suggested. "Even something simple, such as having them sign a proclamation that says 'Hey, it's Lab Week,' creates an awareness that labs exist and that there is a workforce need that legislators know about."
- **Partner with a local university on a project**. George believes that one of the reasons ARUP got the $3 million in funding was because of the clear benefits to medical laboratory science students at the University of Utah. "ARUP is nonprofit and academically affiliated, so it was natural for us. But any lab will be stronger by reaching out to people in the academic world," she observed. "If a lab just goes it alone, it's harder to get sizable grants. However, if you can partner with a university, that's really helpful. And from the political point of view, politicians want to support their local universities."

Using these suggestions allowed ARUP and the University of Utah to think critically about ways to raise awareness of lab staffing issues with key decision-makers who have influence over federal funding. "We want this to be a sustainable program going forward," George said. "We want this to be successful so that we can train not just for ARUP, but really for the whole community." TDR

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Impact of Having More MTs

IT CAN BE DIFFICULT TO ASSIGN A VALUE to having more medical technologists (MTs) and medical laboratory scientists (MLSs), beyond what clinical labs know anecdotally about their own testing volumes or staffing levels.

There are, however, sources of useful data. For example, the **U.S. Bureau of Labor Statistics** noted that, as of 2021, there were 329,200 MTs and medical lab technicians. Additionally, the **American Clinical Laboratory Association** estimated that seven billion diagnostic lab tests are performed annually in the U.S.

Based on those figures—and assuming workers have three weeks of vacation—MTs and other clinical lab bench staff perform an average of 434 diagnostic tests per week.

Once it opens in Salt Lake City, the new Advanced Practice Clinical Laboratory Training Center will accommodate up to 40 more MLS undergraduates each year. Within five years there will be 200 more MLSs in the workplace, with the ability to perform 4.3 million diagnostic tests annually. That is a significant number of additional tests within a community, state, or region.

Laboratories Can Find Value in Use of Leftover Samples

Ovation Research Network offers option for labs to submit remnant samples and possibly earn fees

Barry Wark, PhD

CEO SUMMARY: After testing on behalf of patients, there are often leftover samples. One company developed a platform to enable life science customers to access the samples and associated diagnostic data for research purposes. For clinical labs, the leftover samples provide an opportunity to earn revenue from life science firms.

Holly Magliochetti

DOORS ARE OPENING ON A POTENTIAL NEW SOURCE OF REVENUE for clinical laboratories. Life science research and development organizations are hungry to access patient specimens and associated diagnostic data (where the patient has provided informed consent).

To match the buyers and sellers for these samples and data, **Ovation.io** in Portland, Maine, created the Ovation Research Network. This platform anonymizes and aggregates patient diagnostic data while also collecting leftover testing samples in a central biorepository.

This effort pushes forward precision medicine research and benefits patients in clinical settings who must provide informed consent before their specimens and associated data can be used in further research.

"Real-world clinical data is often limited to the electronic medical record, insurance claims, or prescription data," said Barry Wark, PhD, co-founder and Chief Strategy Officer at Ovation.

"But precision therapies have a genetic component." he noted. "Most of the genetic data that's measured in labs doesn't make it back into the EMR. There's a wealth of information in every specimen that went through a lab—sufficient information to assist precision therapy discovery and development.

Wark spoke at the *2021 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* in San Antonio. His session was titled, "Why Clinical Laboratories Will Propel the Next Evolution of Real-World Data and Drug Development."

Valuable Research Samples

It costs clinical laboratories nothing to join the Ovation Research Network, and they stand to gain value while advancing therapy development by making their remnant samples available for researchers to use.

For these reasons, savvy clinical laboratory managers and pathologists might find the network to be an opportunity to further engage in precision medicine and interact with research organizations and pharma companies.

This was the thinking at **Genetics Institute of America** (GIA) in Delray Beach, Florida, which participates in the Ovation Research Network. One of GIA's executives spoke at the *2021 Executive War College*. "Having alternative channels of revenue within the laboratory has never been more critical than it has been over the last three years," observed Holly Magliochetti, CEO at GIA.

Laboratories involved with the network may be able to earn revenue in two ways:

- Labs that send remnant samples and accompanying diagnostic data for those specimens to Ovation receive origination fees if their samples are used for research.
- If research customers are interested in a series of specimens but further characterization of the samples is needed, Ovation will contract with a lab in the network to perform that work.

Lab origination fees could total tens of thousands of dollars a year, depending on how many samples from a specific lab the researchers request.

Approach to Data

Having de-identified samples already in the Ovation biorepository speeds up the time for Ovation to produce data needed by researchers, Wark said.

"They can commence their trial in days or weeks instead of years. That's the life science customer's incentive to work with the Ovation Research Network," he added. "If Ovation doesn't have the data already and needs to further characterize the samples, we can work with the labs in our network to retrieve and further characterize the samples for a fee. That's another incentive for labs to participate.

"This additional characterized data comes back into Ovation's database," Wark continued, "which we can deliver to our life science customer. It's a win/win arrangement for labs, researchers, and ultimately patients who benefit from new available therapies." *(See the sidebar on the next page for more details on how the Ovation Research Network operates.)*

Ovation will help directly with research requests. A case study posted on its website noted that when a life sciences company needed a genomic sequencing cohort to identify genetic risk factors for inflammatory bowel disease (IBD), Ovation coordinated with several partner labs to convert specimens of patients with possible IBD indications to genomic data. The company's bioinformatics team, and a partner sequencing lab, then performed bioinformatics analysis to identify genetic makeup and perform differential gene expression analysis between inflamed and normal tissues.

The company stated that among the results, "life science researchers were able to access previously unavailable genomic data," due to the work of Ovation and its lab partners.

Better Patient Outcomes

As a lab doing diagnostic testing, one goal of the Genetics Institute of America is to drive precision medicine in cancer and other diseases. "If we can partner with the pharma industry to develop treatment protocols and pharmacological advances that will provide actionable medical treatment as a result of the testing, then that's a win for everyone," Magliochetti observed. "That means more testing and better patient outcomes all the way around."

She said participating in the Ovation Research Network helps fulfill such business and medical community goals.

"Participating in the network provides the benefit of shortening the time required to find subjects for research because they already exist in the biorepository," she stated. "The parameters needed by researchers allow us to quickly identify that data because it already exists. TDR

Contact Barry Wark, PhD, at Barry@ovation.io.

Ovation Research Network Designed to Help Labs Provide Samples and Data to Researchers

By participating in this unique research network, clinical laboratories can submit leftover samples and associated diagnostic data with patient consent into a biorepository. From there, researchers request data about samples that match the type of patients under study.

"The Ovation Research Network's ability to scale and aggregate data from multiple labs allows clinical development to proceed quicker because specific patient profiles are readily available," said Barry Wark, PhD, co-founder and Chief Strategy Officer at Ovation.io, the parent company of Ovation Research Network.

"What if—instead of enrolling patients and making measurements—researchers could go to a database of clinical and genomic data and do their study?" Wark asked. "It might happen 10 times faster and it might cost 10 times less money. Better yet, it can enable industry to bring precision therapies to market faster and more efficiently."

Steps to the Process

Here's an overview of how the Ovation Research Network operates with its partner labs and life science customers:

- Participating clinical laboratories adopt an industry-standard patient notification of secondary use, called "unified patient consent," on test requisition forms and online ordering portals.
- A specimen arrives at a lab and its information is entered into the laboratory information management system (LIMS). While Ovation sells its own LIMS, which integrates easily with the Ovation Research Network, any LIMS can be used to connect to the network.
- After the ordering provider receives the test results, any consented remnant samples can be sent to the network. Ovation checks that patients have consented to the use of de-identified data from their samples and secondary use of the anonymized remnant specimen.
- The specimen then goes into the Ovation Research Network's biorepository, while the associated data goes into the network's database. Both are connected by a unique ID number.
- When a life sciences customer requests a clinical genomic dataset, Ovation pulls relevant specimens out of the biorepository. Originating labs are compensated for the use of the remnant sample and data.
- If needed, Ovation sends the samples to a lab in the network for further characterization. Ovation compensates that lab for such work and delivers the finalized data to the life sciences customer.

Privacy Concerns Are Key

Part of the Ovation Research Network setup revolves around patient consent to have remnant samples and diagnostic data de-identified and used for research.

"Most important, perhaps, is a vetted, carefully constructed legal framework that includes patient notification and consent for a secondary research use of those samples," Wark explained. "And Ovation has the informatics system to track those consents with the specimen and the patient data from their inception through use."

As a software and technology company, Ovation was able to build out the informatics system needed to help run the research network. "We tackled hard informatics problems to collect, store, de-identify, and safely manage the specimen data," he said. "The samples have to be de-identified, put in a biorepository, and made available to research labs as needed. A lot of logistics go into that."

How to Better Communicate with Histology, Physicians

Ordering physicians, pathologists need educating about their roles in the lab specimen lifecycle

Curtiss McNair, PhD

CEO SUMMARY: When ordering physicians or pathologists take issue with histology processes, it's a sign that change is needed somewhere along the line. At American Oncology Network, the resulting communication often centers on bringing greater clarity to the doctors as to how samples are handled in ways that affect transport times and the integrity of the tissue.

CLINICAL LABORATORY OPERATIONS TEAMS HOPING TO IMPROVE COMMUNICATION with physicians—whether they be ordering providers or pathologists—will want to take some notes from **American Oncology Network** (AON).

AON is an alliance of community oncology practices based in Fort Myers, Florida, that operates its own histology laboratory. It has found that making physicians more aware that they are part of a wider process with specimens can lead to positive changes in workflows and quality.

Lab Webinars for Physicians

Improving communication lines between ordering physicians and the lab often boils down to the latter establishing realistic expectations for the former.

"Many physicians have no idea of the life cycle for any type of pathology sample from order to result," noted Curtiss McNair, PhD, Vice President of Laboratory Services at American Oncology Network. "All they know is, 'I ordered it on this day at this time, and I should have a result at this time,' which is often unrealistic.

"We don't always educate our providers and clinicians adequately on the processes in laboratory operations," he continued. "This is why our team, when it comes to histology or other areas of pathology, began offering physician webinars online. This enables us to take them through the processes, close the communication gap, and make their expectations realistic."

Keeping logs of complaints from ordering providers is a useful way to identify potentially unrealistic demands, and identify topics for the online webinars, he added. By contrast, pathologist-based complaints about histology processes take a different tact at AON because those physicians interact directly with bench staff.

"We look at the pathology side of our processes all the time," McNair said. "We collaborate well with our pathology group's medical directors. We are always open to discuss the workflow, what's working, and what's not working.

"We have the type of relationship with pathology where—if their process of signing out cases needs to shift—we do that," he added. "We are also ready to change the process to better support them, or at least suggest that change."

Histology Team Regularly Seeks Opportunities to Improve Specimen Handling and Logistics

Once better communication enables discussion of process changes to move freely, histology operations teams may start pinpointing wasteful activities that, if eliminated, could lead to cost savings.

"For example, logistics is an area that is full of opportunity," said Curtiss McNair, PhD, Vice President of Laboratory Services at American Oncology Network (AON).

"The histology department always wants its samples faster," McNair observed. "And when you start breaking down the process and looking at the options, it becomes evident that having 100% visibility into specimen progress is important. Laboratories need to have eyes on all samples from the moment a sample is taken to the moment it lands in the department that requested it."

Part of AON's approach focuses on knowing how fast or slow a specimen is being delivered and processed. Such data can help better track a case's progress. *(See TDR, "Use Histology Laboratory Data to Illustrate Specimen 'Life Cycle'," Jan. 23, 2023.)*

Audit Logistics Processes

Managers should get creative about how samples come in. Histology labs can review logistics practices to see if there are different ways to receive specimens, regardless of whether it is internal or external delivery. Options include:

- Altering the time of day that external specimens arrive.
- Changing bench staff schedules to accommodate specimen volume.
- Using software to track courier routes. *(See TDR, "Labs Use Internet-of-Things Tools for Specimen Logistics," March 14, 2022.)*

"Laboratories have to get out of the mentality that there's only one way to ship and get samples," McNair noted, comparing this evaluation to a classic 1970s song by singer Paul Simon.

"Labs should approach the whole logistics game of getting samples like the old song, *'50 Ways to Leave Your Lover.'* Instead, it becomes *'50 Ways to Get Your Samples In,'*" McNair quipped. "Taking that mentality opens up creativity and options."

Identify Wasteful Processes

The SAR-CoV-2 pandemic compelled many histology laboratories to examine flawed processes given the huge increase in COVID-19 test volumes.

"COVID forced lab managers to say, 'How can we do this not just more efficiently, but less expensively?'" McNair said. "There are hard-coded activities that just take a long time, such as making the blocks and staining. But how can we get more efficient? How can we find money that we're wasting?"

Histology managers should not equate cutting costs with cutting corners in processes, McNair advised. Instead, efforts should aim to find wasteful activities and make them more efficient.

Such thinking is central to the Lean Six Sigma methodology, which some medical laboratories have used successfully to streamline operations.

McNair urged lab operations managers to not wait to make changes if pathologists raise questions. "If we have a conversation about processes with pathology, the handwriting is already on the wall that we need to change something," he said. "For us, it's usually not an arm-wrestling match over the need to do something differently." TDR

Contact Curtiss McNair, PhD, at curtiss.mcnair@aoncology.com.

Lab Market Update

Enzo Biochem's Lab Business Sold to Labcorp for $146M

COMMERCIAL LABORATORY CONSOLIDATION CONTINUES, this time with news earlier this month that New York City-based **Enzo Biochem** agreed to sell its clinical laboratory business to **Labcorp**.

The deal points to the problem many clinical laboratories have as demand for SARS-CoV-2 testing evaporates, along with the decline in revenue associated with these tests.

$146 Million Acquisition

The price of the Labcorp transaction was $146 million, according to a **U.S. Security and Exchange Commission** filing posted by Enzo. The deal was announced on March 16.

Enzo Biochem is a biotechnology company with business lines for life sciences and reference laboratory work. With the sale of the clinical lab division, Enzo will put more focus on life sciences and therapeutics.

"In 2022, Enzo Biochem initiated a strategic initiative to restructure operations to target business areas and industry sectors representing major growth opportunities," the company said in a news release.

"The company's remaining operating segment—Enzo Life Sciences—supplies a complete portfolio of products and services that are critical and extensively used in drug discovery, development, and translational research applications," the release continues.

Enzo tried to provide a local alternative to the larger national labs, such as Labcorp and **Quest Diagnostics**, in the highly competitive tri-state market that includes New York, New Jersey, and Connecticut. Enzo determined the market value for this region was $1.8 billion.

Q2 Lab Earnings Down 66%

Publicly-reported financial results confirmed that the company saw greater opportunity for life sciences revenue while at the same time experiencing losses in the clinical lab business.

For Enzo's Q2 2023, which ended on Jan. 31, 2023, the company reported the following:

- Total quarterly revenue of $16.3 million, a drop of 52% compared to Q2 2022.
- $8.8 million for clinical lab services (down 66% from Q2 2022).
- $7.5 million for life sciences (flat compared to 2022).

Meanwhile, Q1 2023 results broke down as follows:

- Total revenue of $18.3 million (a decrease of 31% from Q1 2022).
- $11.2 million for clinical lab services (down 43%).
- $7.1 million for life sciences (up 9%).

COVID-19 Revenue Down

At press time, Enzo CEO Hamid Erfanian did not respond to questions from THE DARK REPORT about the Labcorp/Enzo Biochem agreement.

However, during a Q1 earnings call with investors on Dec. 13, it was clear there was frustration about the drop in COVID-19 testing sales and hints that Enzo was exploring options with other companies. Enzo has yet to conduct a Q2 2023 investor call.

Revenue associated with SARS-CoV-2 testing at Enzo's laboratory business collapsed by 91% from Q1 2022 to Q1 2023. These results are consistent with what much of the lab industry has experienced, as noted by THE DARK REPORT over the past year. *(See TDR, "IVD Firms Grow During 2022, But COVID-19 Revenue Dropped," May 16, 2022.)*

This development was addressed by Enzo's CEO. "We continue to cycle through some anticipated difficult comparisons driven by historical COVID revenues, which will anniversary in the fourth quarter of [FY 2023]," Erfanian said during the December earnings call. "COVID revenues declined from $9.2 million in Q1 fiscal year 2022 to $0.8 million in Q1 fiscal year 2023, which accounted for the full decline in the year-over-year revenues."

Nonetheless, he identified several clinical lab areas as bright spots, including a new menu of molecular diagnostic tests, direct-to-consumer tests, and, ironically, the lab's community roots in the New York area.

"This is an area where our combination of the full range of testing capabilities with the convenience and personalized service of a local, community-based laboratory operation differentiate our service offerings," he said.

Takeaways from Enzo's Deal

Enzo's deal with Labcorp offers clinical laboratory managers and pathologists two lessons:

- Successful clinical laboratories must proactively uncover new revenue that offsets losses of COVID-19 business, particularly in those organizations where administrators and executives are focused on quarter-over-quarter business comparisons.
- It is useful for clinical laboratory leaders to recognize what investors currently pay to acquire a book of lab test clients. Recent sales of such diagnostic businesses often generate sales prices in excess of $100 million to the seller. Assigning this type of benchmark may provide justification for further investment in laboratory operations.

The Enzo/Labcorp deal highlights the difficulty independent labs face in offsetting the ongoing decline in COVID-19 testing and associated revenue. TDR

Enzo Deal is Latest of Labcorp Acquisitions

LABCORP IN BURLINGTON, NORTH CAROLINA, has been busy since 2021 with acquisitions of laboratory companies and lab outreach programs in hospitals. The recent acquisition of Enzo Biochem's clinical laboratory business fits in squarely with long-term business strategies at Labcorp.

"The pipeline for hospital and local laboratory acquisition and investment is robust and will be a key area of opportunity for growth in 2023 and beyond," said Labcorp CEO Adam Schechter during a Feb. 16 earnings call.

The company reported spending $1.2 billion on acquisitions during 2022. Many of those deals involved the purchase of laboratory outreach programs from hospital systems and/or taking over hospital lab operations.

The most prominent of those announcements was a deal in which Labcorp began to manage nearly 100 hospital labs for **Ascension Health** based in St. Louis and acquired the laboratory outreach business at a number of Ascension locations.

Labcorp paid Ascension Health about $400 million for that outreach lab business. Yet already, the Ascension deal appears to be heading toward profitability, as Schechter predicted that Labcorp will earn $550 million to $600 million in 2023 in Ascension-related revenue. *(See TDR, "Labcorp: Ascension Deal Will Earn $550 Million in 2023," March 6, 2023.)*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Clinical laboratory leaders watching at-home care evolve should note the new partnership between **Best Buy** and **Atrium Health** in Charlotte, North Carolina. As part of the deal, **Best Buy Health**, a division of the retailer, will assist patients in setting up the technology pieces of Atrium's Hospital-at-Home program. The partnership enables community paramedics and nurses from Atrium to visit patients in their homes and take data from wearable monitoring devices. This allows caregivers to check vital signs as if patients were in a hospital. From there, the at-home care team can give electrocardiograms, provide medications, and draw blood for diagnostic tests, among other services that are typically available to inpatients at hospitals.

MORE ON: *Best Buy Deal*

Specially trained Best Buy tech employees, some from the **Geek Squad**, will visit at-home patient to set up wearable devices and tie them into remote monitoring systems. Best Buy Health's telehealth network will bring complementary capabilities to clinical services, Atrium noted in a news release. It also touted Best Buy's experience in customer service as a benefit to at-home patients. Best Buy reps will never provide actual heatlhcare to patients.

FDA CLEARS POINT-OF-CARE TEST FOR FENTANYL

The ever-increasing abuse of fentanyl has motivated a company to develop a point-of-care (POC) test that received clearance in March from the **Food and Drug Administration** (FDA). The test, developed by **Shenzhen Superbio Technology** in China, is a fluorescence immunoassay that detects fentanyl in urine using a POC analyzer. **Carolina Liquid Chemistries Corp.** in Greensboro, North Carolina, will distribute the test in the U.S. Overdoses from synthetic opiates, such as fentanyl, have skyrocketed over the last decade, with 70,601 overdose deaths reported in 2021, according to the **National Institutes of Health**.

TRANSITIONS

- Digital pathology and artificial intelligence firm **PathAI** in Boston announced that Nick Anderson, PhD, has joined as Vice President of Regulatory Affairs, and Hisani Madison, PhD, MPH, has joined as Franchise Head of Precision Oncology. Anderson formerly worked at the FDA and **Becton Dickinson**, while Madison also worked at the FDA and **AstraZeneca**.

- Connie Stec, H(ASCP), has been named Laboratory Director at **AdventHealth** Hendersonville in North Carolina. She joined AdventHealth in 2021 and previously held lab supervisor roles at **ProMedica** and **University of Toledo Medical Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 17, 2023.

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How Old School Lab Rules Evolved into New School Lab Rules: Ways to Transition Your Lab Through Today's Disrupters in Healthcare

Today's healthcare system presents clinical laboratories and pathology groups with great opportunities to better serve patients, contribute to improved outcomes, and be paid for these contributions. That's the upside for labs!

But changes in healthcare and how consumers use health services is the downside for labs. Consumer self-directed testing, retail pharmacies pursuing their own primary care offerings, and payers' restrictive prior-authorization requirements are just a few threats for which labs need an effective response.

During this session, you'll learn which opportunities are best for your lab to pursue and which threats require immediate and specific responses. You'll hear practical advice and receive proven steps to keep your lab at the forefront of clinical excellence and financial stability. Bring your team and ensure your place by registering today at *www.ExecutiveWarCollege.com*!

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UPCOMING...

- ***CMS' proposed new rule to define physicians' electronic signatures has big implications for labs.***
- ***More mergers and consolidations predicted involving large integrated health systems.***
- ***Keys to success in using artificial intelligence to scale next-generation sequencing.***