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SMALL AND MEDIUM PHARMACEUTICAL COMPANIES (SMBs) HAVE AN ALLY THEY CAN RELY ON IN LINICAL AMERICAS

The efforts of a contract research organization can be the difference between a failed idea and the successful launch of a new drug. CROs (clinical research organizations) support the pharmaceutical, biotech, and medical device industries with invaluable guidance on everything from protocol development and project management to clinical studies and regulatory affairs. CROs are a vital bridge between the science of development and the business of bringing medicine to market.

The needs of startups and small and medium-sized businesses (SMBs) in the pharmaceutical space are different than those of large legacy companies fully immersed in the intricacies of moving from development and successful clinical studies to market approval, and SMBs need steering from CROs with an understanding of their specific needs. Linical Americas is one such company.

Here's how CEO of Linical Americas Vita Lanoce, MS, synthesized the unique position of startups and SMBs looking to bring a new product to market. "Startup companies begin

from different spots. They could be a university or private lab where a discovery is made and they build out a company to further their research, or investors entering into a licensing agreement to further develop a product that has promise. No matter where they begin, most startup companies are made up of a handful of scientists and researchers, so they have basic needs.

"Obviously one of those needs is funding, but more so they need the experience that a CRO can bring to them. They are scientists and researchers, people that know their theory—they've proven it, they need to move their concept forward—but where do they start? Companies like Linical Americas can help them," she said.

"Another essential need is to obtain good early results, and what I mean by that is ensuring researchers can prove their hypothesis in a way that provides them with the right information. Linical Americas helps by getting early stage clinical studies started swiftly because it is so critical for companies to have the

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VITA LANOCE, MS, CEO

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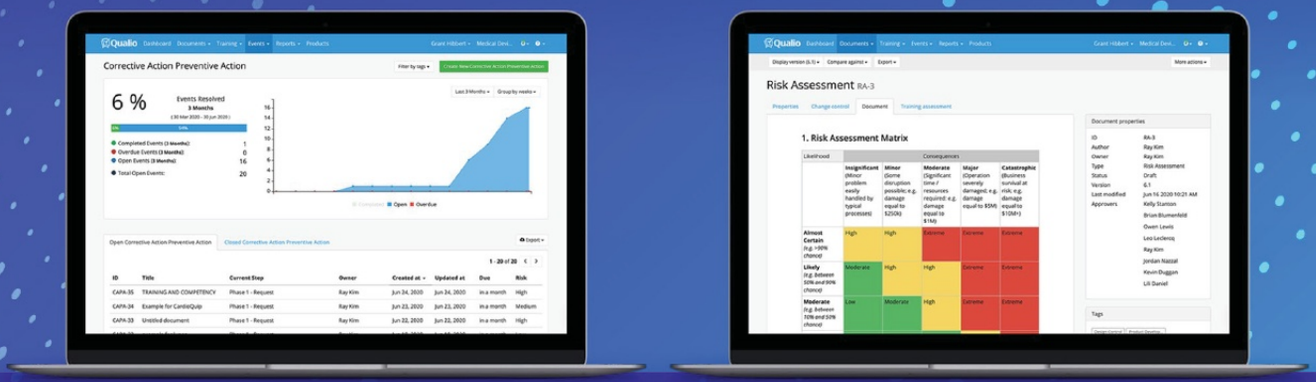

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>
> - Tyler Cochran, Head of Quality, Linical Americas

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data to make appropriate decisions. Is the decision to move the research program forward? Is the decision to stop development because it is not going to prove what they originally intended? Do they need to modify their clinical development program? It is a very deep relationship that we establish from the very beginning and foster throughout to ensure they are positioned with the information needed to make important decisions along the way."

Established in mid-2018, Linical Americas is the culmination of a merger between Linical and Accelovance that created a midsize CRO with a robust global reach throughout North America, Europe, and Asia-Pacific. Lanoce, formerly the COO for Accelovance, is a seasoned veteran in clinical research with prior stints at Covance, Bristol Myers Squibb, and Radiant Development.

The global unification of the company, which is headquartered in Osaka, Japan, created a full service international organization specializing in assisting firms that develop therapeutics for phase I-IV oncology, infectious disease, and CNS including pain, psychiatric, and neurology based studies. Linical Americas also offers comprehensive patient engagement solutions as well as pharmacovigilance, also known as drug safety solutions.

"What's great about being part of Linical Americas is that we have

the flexibility to work on early phase research regionally and expand with our clients when they progress from that early stage to large-scale multinational studies, particularly in Asia with a strong presence in Japan; this is a real benefit," she noted.

Linical Americas has successfully integrated within the Linical organization and is already winning awards. In 2020, it picked up a CRO Leadership Award for Overall Compatibility, for exceeding customer expectations across both big and small pharma customers.

GUIDANCE WITH CARE, FOR THE BRIGHTEST POSSIBLE FUTURE

Lanoce emphasized that when it comes to funding, startups seek commitments in the $500,000 to $2 million range to conduct proof

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of concept studies. "As companies start to move from proof of concept along their clinical development pathway, they will seek funding of $20 million-plus," she said. At this stage, some small players may continue to tap into private funding, move toward an IPO, or look to larger companies to create a partnership or licensing agreement. Whatever direction they choose, ensuring they have the financial resources to move from the clinical development program to gain agency approval and eventually to market is a long road.

"CROs help guide small companies and startups through the very detailed process of how to navigate the clinical development pathway to obtain regulatory approval. Today innovation and new clinical development has shifted to a larger percent being startups and small to mid-sized companies, which is a big change from where the big pharma R&D space used to be 20-25 years ago, with discovery and clinical development under one roof." With a groundswell of new approaches incubating, smaller developers need an expert set of hands to move through the regulatory and clinical development processes.

"There are so many aspects of how we achieve success for our clients and their clinical development programs. We focus on understanding their needs and goals, ensuring the budgets and timelines fit. We are continuously verifying their needs, matching solutions to those needs toward achievement of their goals."

The burden of examining regulatory strategies, understanding competing therapies, designing protocols, and the vagaries of drug approval are hard on even the most ambitious aspiring market entrants. Linical Americas helps companies demonstrate that their drug is, in Lanoce's words, "effective, safe, and acceptable to regulatory agencies." Having a CRO with that expertise to ensure they are positioned for success is really important.

"It's also important to guide companies through the complexities, variables, and nuances to navigate through the clinical development pathway.

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BEING STARTUPS
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RMA R&D SPACE USED
OVERY AND CLINICAL

VITA LANOCE

It starts with regulatory consultation but goes far beyond. Selecting the right sites is critical. Linical Americas has established deep relationships with sites that really go beyond sending questionnaires or generating a list from a laboratory. Talking with the investigator, getting their input on the protocol, and ensuring it is feasible to enroll patients in the study provides the client better comfort and assurances toward achievement of their goals. We meet with and identify the right investigator; one that not only understands the protocol and nuances but has input to ensure they are successful and the study is conducted with quality in mind."

Like its competition, Linical Americas works with partners that provide an array of services in support of clinical studies they do not do in-house. These partner companies deploy powerful clinical trial technologies such as EDC, ePRO, direct data capture, and much more. "Linical Americas has developed strong relationships with our partners to ensure access to the right electronic solution, not just a solution. We work with many different vendor partners and can provide consultative advice on selecting the best vendor for a client's particular situation. A great example would be Viedoc. They

“NAVIGATING THE COMPLEX TRIAL PROCESS IS WHAT WE EXCEL AT, SO WE MAKE SURE THAT OUR CLIENTS HAVE THE LATEST TECHNOLOGY AND SYSTEMS IN ADDITION TO ACCESS TO THE RIGHT INVESTIGATORS AND PATIENTS.” VITA LANOCE

have a purpose-built EDC system with add on features that provide important solutions. For instance, capturing patient reported outcomes can be challenging. Viedoc allows study participants to use their own devices to access diaries and questionnaires. Partnerships like this ensure we select the right solution for the intended purpose, so data is captured accurately, with consistency across the entire project, and is reviewed by the CRO and client to ensure quality,” she confirmed. “Navigating the complex trial process is what we excel at, so we make sure that our clients have the latest technology and systems in addition to access to the right investigators and patients.”

On the quality assurance side, Linical Americas is committed to a quality culture. This culture is embraced globally through an internal Quality Management System (QMS) using the Qualio platform. “Quality is at the heart of everything we do. Having a platform for training and compliance is very important. Qualio’s platform provides Linical Americas the ability to meet our corporate, project, and people objectives, while giving clients the assurances they look for to secure proper oversight of the work we perform on their behalf.”

INNOVATION ARISING FROM THE PANDEMIC

"When the pandemic emerged, Linical Americas was able to pivot quickly, which was necessary for oncology and other therapeutic areas for which we have ongoing studies or new studies starting up. This created an opportunity to push through new and innovative ways to use technology to start and restart studies. Patients are very interested in participating in studies in indications other than COVID. They have real issues that need real attention, and while many studies went on pause, by adding electronic solutions and innovative ways to start up new projects as well as alternatives to conduct clinical studies, we helped patients remain in active in clinical studies, continue to enroll in new clinical studies, and feel safe," Lanoce said.

"With telemedicine and virtual data collection, we aim to make things easier for the patient. It's important to be flexible, think through potential problems before they arise, and align the associated solutions to ensure our teams are proactive instead of reactive. We had to reimagine how we start up, monitor, and manage clinical studies. Through innovative ways to be more efficient and utilize technology available to us in a different way, we were able to quickly restart projects and ensure that clinical studies continue for many diseases without a current perfect solution."

"THROUGH INNOVATIVE WAYS TO BE TECHNOLOGY AVAILABLE TO US IN A TO QUICKLY RESTART PROJECTS AND CONTINUE FOR MANY DISEASES WITH SOLUTION." VITA LANOCE

There will be medical conditions that emerge directly from the effects of the novel coronavirus, and they will likely require novel therapeutics. Linical Americas is there to see those efforts succeed. "We look at the expertise we need today as well as areas of research that we may see in the future. This is where we build upon our knowledge and experience, plan ahead, and focus on ensuring we are positioned to support client needs for the future." With Linical Americas helping to steer the world's brightest minds to success, it will be a bright future indeed. ■

MORE EFFICIENT AND UTILIZE
DIFFERENT WAY WE WERE ABLE
ENSURE THAT CLINICAL STUDIES
IOUT A CURRENT PERFECT

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