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Spotlight on oncology drug development & its future

Why an informed, holistic view is needed to succeed in today's complex and dynamic landscape

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By Allucent

Of the nearly 7,000 clinical programs reported in 2022, 43% are in oncology – signaling the tremendous need for and promise of new cancer treatments.

Jessica Lee is the vice president of regulatory strategy and head of cell and gene therapy at the specialized Clinical Research Organization (CRO) leader, Allucent. Here she discusses how her background informs her current work, and what she sees as the biggest opportunities and special considerations ahead for small and mid-sized biotech companies in oncology.

Can you tell us about your background, and how you apply the various facets of your previous work in oncology to what you're doing now?

My 30 years of experience in oncology includes basic research, significant time spent in clinical practice and at the FDA, and most recently working with industry. I feel fortunate to have had such a deep and diverse career in oncology and what led me down this path is that I'm motivated by new challenges and want to use my expertise to help as many people as possible.

My time in clinical practice gave me an invaluable window into cancer patients' needs. I'll always be an oncologist at heart, so helping to bring innovative, potentially life-changing or life-saving medicines to patients is what drives me.

I also feel fortunate to have worked at the FDA's Center for Biologics Evaluation and Research (CBER) during a groundbreaking time in oncology. When I started, we were just beginning to see the first wave of revolution in immune oncology – and I was there for the exponential growth in cell and gene therapy (CGT) that followed.

During this time, I saw many new innovative modalities navigate through the regulatory process across all different types of cancers. It was gratifying work that enabled me to bring a specialized perspective to what I'm doing now at Allucent – not just from a regulatory standpoint, but also for things like trial design, protocol development and patient safety because if the details aren't thought through carefully and early, they can have unfavorable implications for sponsors and patients alike.

What makes drug development in oncology so complex, and what special considerations should companies working in this area keep in mind?

It's a very exciting time in cancer drug development because we now have a much better understanding of the disease. We know there is tremendous variability between individual patients, even among those with the same type of cancer. This means that, increasingly, we can tailor treatments to individual patients, specific biomarkers and disease characteristics.

It also means that each new product has to consider individual variations and additionally most of the investigational CGTs are fresh from the bench. So, there are a lot of uncharted territories and the safety considerations and clinical development plan for each therapy must be highly customized. This also includes new combination treatments, which bring another layer of complexity to designing clinical studies and mitigating potential safety concerns. Because science is progressing so rapidly, things are also changing very quickly on the regulatory side – which means you have to anticipate potentially changing regulatory requirements and ways to get ahead of that.

This is why having a holistic view is so important – understanding the science, patient needs, potential safety issues and the perspective of regulators. I'm able to take all of that and consider the unique attributes of each product to provide counsel to our clients about the most effective and efficient path forward. It's very gratifying to be able to bring the totality of my experience to the table for our biotech partners – and give them honest, objective counsel that can help put them on the path toward success.

What are you most excited about heading into 2023?

I'm really looking forward to seeing the next generation of cancer treatments progress through clinical development. I see so many innovative ideas coming in, and there's very exciting work happening right now, including advancing cell therapies (e.g., CART, TCR, and TIL, etc.) into the realm of solid tumor, the advancement of off-the-shelf cellular products (e.g., allo-CART) to address potential manufacturing-related issues and novel combination therapies to overcome potential tumor resistance. So, I'm excited to see what 2023 holds and very optimistic about our ability to deliver new cancer treatments to patients in need.