Driving More Effective Clinical Trials To Impact Lives

The blending of science and technology is changing the life sciences industry at an extraordinary pace. Clinical trials are getting more complex, both in design and in their conduct. Never before have we seen the growing number of systems and new technologies used within clinical research. And the need for greater efficiencies to get new therapies, whether they be medicines or devices, to patients has never been more pronounced.

SAM SRIVASTAVA, CEO, WCG

Championing An Integrated Approach

The life sciences industry has the capability to ensure the right patients, clinicians, and research sites – in the right locations – are in the right clinical trials at the right time. However, while artificial intelligence, machine learning, and other novel technologies are game changers, they alone are not a magic bullet that can be used to truly transform clinical research.

Connectivity across all research stakeholders remains critical. For sponsors to be successful in the future, Sam Srivastava, chief executive officer of WCG, highlights the need for a connected ecosystem that leverages deep expertise, services, data, and technology to create a truly high-performing clinical research network on a global scale. "In today's environment," remarks Srivastava, "pain points are integrated and connected, affecting multiple groups, so there is a need to break silos and connect all trial stakeholders."

Driving this ecosystem connectivity and interoperability between often disparate electronic systems to accelerate the delivery of needed new therapies to patients, while maintaining scientific rigor and the highest quality protections for study participants, is WCG's raison d'être.

What do clinical trials of the future look like and how do we get there? How can we be the catalysts of change that make a meaningful difference to patients across the globe? These are the questions WCG asks, Srivastava explains. "It is about optimization on both a macro and micro level."

A Changed Mindset

One of the side effects of COVID-19 is that the global pharmaceutical industry was forced to embrace and invest in innovative clinical research methods and new technology tools. Currently, much of the discussion on these methods and tools has focused on decentralized clinical trials (DCTs).

However, Srivastava has a different view and focus, based not only on his experience at WCG, but also having spent many years on the care delivery side of the industry. He feels that the intense focus on DCTs is a limiting one. "DCTs currently represent a small portion of all the clinical trials in the marketplace." He notes that due to the current disease burden on patients, comorbidities, and challenges of many infectious and chronic diseases, the DCT model often does not lend itself to all clinical trials. "Hybrid trials extend trial points of care beyond the site and specialist, with technology to engage, care, and provide biometric feedback remotely or in the home. They are the real key to the future and have the opportunity to transform research as we know it today."

By using technological advances such as eConsent, remote patient monitoring, and telemedicine, the industry is poised to reach more targeted patient populations. However, Srivastava explains that more work needs to be done. "Researchers are still focused on federated point solutions. They still work on single issues and then in silos," he says. The clinical research area is just starting to embrace integrating care with clinical outcomes.

Srivastava suggests moving away from federated silos and centralized models, and towards integrated solutions. "Such a change improves the overall experience for the participant, and the overall ability of a site, a provider, or an investigator to deliver services and research more effectively." Under his leadership, WCG is increasing the velocity, efficiency, and effectiveness of clinical trials with such integrated solutions.

Integration And Collaboration

Srivastava sees WCG's role not as a provider but a convener and partner to help biopharma, CROs, and sites strengthen existing systems as a drive to true interoperability between them. This is largely due to the company's global portfolio platform of solutions, which includes ethical and scientific review services, clinical research solutions, deep expertise, data, and insights. "Through WCG's access to 5,000+ sponsors, 4,000+ sites and networks, and dozens of patient advocacy groups globally, we realized that our role shifted from a pure-play solutions provider to a convener of stakeholders," he explains.

The goal is to use technology, data, insights, and innovative workflows to improve efficiency and outcomes, and ultimately to

change behavior. To achieve this, the needs of all stakeholders must be accounted for while collaborating. WCG, for example, has formed partnerships with entities such as Global Alzheimer's Platform Foundation and Florence Healthcare, to actively support clinical research sites serving underrepresented communities by providing a variety of services, such as training resources, workflow support, and automation platforms.

Understanding that all stakeholders must have access and support, WCG is continuing to integrate more patients into its ecosystem, allowing for increased access to a larger patient recruitment pool for clinical studies. Besides providing needed institutional review board expertise and capabilities, WCG's partnership with The Michael J. Fox Foundation for Parkinson's Research also helps patients to find suitable trials, thus further demonstrating the success of its network design. This type of collaboration for a global ecosystem not only solves one issue for one stakeholder, such as a sponsor, but is able to impact many others.

Technology Isn't Enough On Its Own

Technology is a prerequisite for this undertaking, to bring the clinical research community together, but technological solutions are not enough on their own. What is equally important, but also a potential pitfall, is expertise, Srivastava states. "I think technology solutions aren't enough on their own. You must have expertise and data advisory capabilities to truly meet the needs of each unique trial and stakeholder."

An example of this is WCG Investigator Space. "It's a platform for site training, safety reporting and communication," Srivastava explains "If we're able to dock into multiple academic medical centers and their research investigators, we're able to educate them quickly on protocols, inclusion criteria, exclusion criteria, etc. They're then able to get up to speed more quickly and leverage the best possible information to ask the right set of questions and make an informed decision about whether to enroll a patient. This is an important piece to ensuring the needed flexibility and agility."

By working with companies that are constantly evaluating new technologies and adopting them, stakeholders are continually able to be innovative, agile, and efficient. WCG is an early adopter of technology and pioneering shifts in the industry to enable interoperability between a wide range of novel clinical trial solutions. "As a convenor, we have a technological wrap around a set of experts," Srivastava notes. "We have the ability to connect into how a sponsor, clinical research site, or organization works today."

Equally important is expertise to review the data in an advisory capacity, that meets the needs of, and solves problems for, each stakeholder and trial. It is such flexibility, agility, and data advisory capabilities which create a successful partnership and global collaboration.

Driving Health Equity

Diversity, equity, and inclusion (DE&I) are some of the most critical topics in medical research today, yet many populations remain severely underrepresented in clinical trials. While minority communities (racial and ethnic) make up nearly 40 percent of the U.S. population, an overwhelming 75 percent of the 32,000 clinical trial participants for 53 new drugs approved in 2020 were white. This persistent lack of diversity in clinical trials means many therapies are never tested on the very patients for whom they are intended.

A trusted partner in trial participant protection for more than 50 years, WCG's dedicated patient advocacy group and subject matter experts are working with stakeholders across the ecosystem to overcome the challenges involved in driving greater health equity. These obstacles range from a lack of physical access to clinical trial sites to a lack of trust in pharmaceutical companies and medical institutions conducting research and a lack of proper community outreach.

Leveraging its deep expertise and broad network, reaching into communities and meeting patients where they are, WCG is building a foundation for the future of clinical research, one that represents patients from all walks of life. "The next chapter of DE&I within clinical research goes beyond program management to rethinking protocols and trial designs from the ground up, around the personalization of clinical research," Srivastava states. "Because we've made investments on the patient side and on working with sites more locally, across the globe, I believe WCG is uniquely positioned to understand the challenges of the social determinants of health. Because of these investments, we support those who design inclusion criteria, exclusion criteria, and clinical endpoints that serve all people, not just the majority."

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Mobilizing The Ecosystem

Clinical trials take a village. The pandemic showed what's possible when all stakeholders come together. For its part, WCG remains focused on mobilizing ecosystem collaborators who can together streamline study operations and data collection, resolve interoperability challenges, increase diversity and inclusion in clinical research, and reduce the burden on participating patients and sites, improving the experience for them.

"Working together, we can increase access, efficiency, and the quality of clinical trials," Srivastava notes, "not just the solution for one stakeholder, but across the industry, for the benefit of the patients we all serve."