

# North Carolina Biotechnology Center

## Worldwide Clinical Trials Uses AI with Oncology, Rare Disease Precision



**WORLDWIDE**  
CLINICAL TRIALS

Written by Elizabeth Witherspoon, Ph.D.

**Worldwide Clinical Trials, a Morrisville clinical research organization with operations in 60 countries, has made two significant announcements regarding its push to address the rapidly changing and increasing needs in oncology and rare disease clinical trials.**

First, the company has formed a strategic alliance with Deep Lens, a Columbus, Ohio-based artificial intelligence (AI)-driven digital pathology company that focuses on diagnosis confirmation and clinical trial recruitment.

Second, it has added Gaurav Sharma, M.Pharm, PMP, C.Sci, FIBMS, MICR, in the new role of senior vice president and therapeutic area leader, rare disease and oncology. “This represents an expansion and greater focus by the company on the special needs of oncology and rare disease research,” said Meghann Howland, vice president, therapeutic strategy oncology, rare disease and inflammatory medicine/worldwide.

More than 14,000 oncology clinical trials are actively recruiting patients, according to clinicaltrials.gov. However, estimates put the rate of participation for adult cancer patients at less than 5 percent. Patient recruitment for trials

remains a time-intensive, costly barrier to the execution of drug development programs. Meanwhile, oncologists and those of their patients who have exhausted all other available approved therapies need quick, streamlined access to clinical research as a care option.



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Deep Lens co-founder and chief scientific officer

Furthermore, with the advent of personalized medicine and targeting of certain genetic mutations, the companies intend to pair Worldwide’s expertise in clinical cancer research and global clinical trial operations with the Deep Lens VIPER AI-driven digital pathology platform. Their goal is to support a new ecosystem for sponsors, researchers and care teams to accelerate cancer diagnoses and present clearer treatment and clinical trial options earlier in the process. They also want to support more-complex research designs, such as “basket” and “umbrella,” that enroll patients based on genetic characteristics and other biomarkers of their cancer types.

Rare disease and oncology trials often share the same challenges: vulnerable populations, a global focus with multiple trial sites, and an urgent need to adapt clinical trial designs to the complexities of conducting research in these populations. Basket clinical trials test the effect of one drug



Gaurav Sharma  
Worldwide Clinical Trials photos

on a single genetic mutation across a variety of tumor types, as opposed to clinical trials that include only breast cancer or brain cancer patients, for example. Umbrella trials have many different treatment arms based upon patients' type of cancer and the specific molecular makeup of each of their cancers, according to the American Society of Clinical Oncology.



Deep Lens' VIPER technology combines AI and digital pathology workflow and collaboration capabilities to characterize tumors and identify patients and appropriate clinical trials for providers to present as options at the time of diagnosis. It was built by pathology groups from around the

world collaboration with the innovation group at one of the largest pediatric oncology facilities in the United States, Nationwide Children's Hospital (NCH) in Columbus, Ohio. They focused on specific tumor types and subtypes and NCH played the role of global biospecimen repository and facilitated research projects globally. Those participants, at more than 65 major institutions, helped forge the requirements that today make up the VIPER platform.

VIPER also was used in The Cancer Genome Atlas project, the National Cancer Institute's (NCI) landmark cancer genomics program that molecularly characterized over 20,000 primary cancer and matched normal samples spanning 33 cancer types for a publicly accessible database to drive cancer research nationwide. This was a joint effort between NCI and the National Human Genome Research Institute, which began in 2006.

"There is a lot of sponsored research potential out there where we can find patients who qualify for precision and personalized medicine at an earlier time," said T.J. Bowen, Ph.D., Deep Lens co-founder and chief scientific officer. "We have a lot of capabilities we didn't have three or five years ago."

This expansion and strategic alliance with Deep Lens has spurred Worldwide to separate its oncology and rare disease clinical trial operations into a new therapeutic area headed by Sharma, who last served as senior vice president and head of global project management at Premier Research and has held several senior roles of increasing responsibility with ICON plc, Takeda and PAREXEL.

"Gaurav's education, clinical and research experiences place him in a select group of leaders that can complete complex early-phase trials that are important to the development of new treatments for patients with cancer," said Peter Benton, Worldwide president and COO.

## About Worldwide and Deep Lens

Worldwide employs more than 1,600 around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia. It is a full-service, midsize, global CRO operating in 60 countries. It has 191 employees in North Carolina, 121 of them based at the Morrisville headquarters. The company executes studies across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, immune-mediated inflammatory disorders, oncology and rare diseases.

Deep Lens provides the VIPER technology to pathology groups and academic medical centers for training, education and to improve workflow. In turn, this data enables the company to confirm diagnoses and provide precision medicine-level data to providers at the time of diagnosis along with information about available clinical trial opportunities appropriate to individual patients.



Worldwide headquarters in Morrisville

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**Jim Shamp**, director, public relations, corporate communications ([jim\\_shamp@ncbiotech.org](mailto:jim_shamp@ncbiotech.org))

15 T.W. Alexander Drive | Research Triangle Park, NC 27709-3547 | [ncbiotech.org](http://ncbiotech.org)  
Asheville · Charlotte · Greenville · Wilmington · Winston-Salem