MedGenome Begins to Ramp Up Single-Cell, Immuno-Oncology Research

Feb 23, 2018 | Monica Heger

Premium

SAN FRANCISCO (GenomeWeb) – Genomic diagnostics and research firm MedGenome plans to ramp up its research in the single-cell and immuno-oncology spaces while continuing to make inroads in the clinical genomic testing market in India.

The company has next-generation sequencing laboratories in Bangalore, India; Foster City, California; and Singapore. MedGenome CEO Sam Santhosh said that the Bangalore lab is primarily a diagnostics lab, while its large research projects are run mainly from its Foster City laboratory.

Last year, the firm raised $30 million in a Series C financing round, which it has used in part to expand its Foster City lab and purchase new technology, most notably 10x Genomics' Chromium system and Illumina's NovaSeq instrument.

Santhosh said that the company plans to focus upcoming research in the immuno-oncology space, including using single-cell sequencing techniques to analyze the tumor microenvironment.

The firm has struck a few agreements with currently unnamed academic and commercial organizations for several single-cell sequencing projects for a variety of solid tumors. These projects focus especially on immune cell sequencing to understand how the presence, absences, and types of T cells correlate with a patient's prognosis or response to therapy.

One research goal, he said, would be to look for gene expression signatures that are specific to the various cells in the tumor microenvironment, such as immune and stromal cells, and then use those signatures to determine the prevalence of various cell types in specific tumors. In addition, the firm plans to assess T cell activity to see how that correlates with patient prognosis or therapy response.

In previous studies by MedGenome, researchers have been able to "fine-tune gene signatures" using bulk RNA sequencing, he said. "But single-cell sequencing will be an exciting add-on" that will increase the resolution.

The initial single-cell sequencing research will focus on cancer, he said, but eventually, the firm would apply the technology to study other diseases, such as autoimmune disorders or infectious disease.

Currently, the Chromium system is operated out of the Foster City laboratory, but Santhosh anticipates eventually implementing the technology at its other locations as well. Typically, new technology is introduced first in the Foster City laboratory and then, when the firm is more comfortable with the technology, it also moves it to the other locations, he said.

Aside from cancer, MedGenome has conducted research on inherited disease, including a collaboration with Genentech and the Madras Diabetes Research Foundation in Chennai, India, on an inherited form of diabetes. Last week, the group published a study in *BMC Medical Genetics* in which it identified both

known and novel variants in individuals diagnosed with mature-onset diabetes of the young. The researchers performed targeted exome or whole-exome, as well as low-coverage whole-genome sequencing, on a cohort of 289 Indian individuals, including 152 with a clinical diagnosis of MODY, and found that the genes HNF1A and ABCC8 were the most frequently mutated MODY-related genes from the South Indian cohort, explaining about 11 percent of cases. The group also found evidence for around 10 novel disease-related genes. Functional testing of one, NKX6-1, indicated it was potentially causative, but would require further validation.

The paper underscored the importance of studying genetic disease in different populations. For instance, in Caucasian populations, mutations to HNF1A and GCK are the most prevalent, accounting for between 70 percent and 80 percent of cases. Smaller studies have hinted that substantially fewer cases in South Asian populations can be explained by those two genes, which this study confirmed. In addition, the group found variants in genes that have been implicated in other forms of diabetes, including NKX6-1.

MedGenome is also a participant in the population sequencing project GenomeAsia 100K, which was launched in 2016 to sequence 100,000 individuals from all geographic regions of Asia to capture population diversity. Santhosh said that an initial publication describing the sequencing and analysis of around 2,000 genomes is currently under review for publication in a peer-reviewed journal. The consortium has since completed around 10,000 genomes from the various geographic regions in Asia and is now working to collect samples from clinical cohorts comprising cardiovascular disease, diabetes, and some cancers.

Santhosh said that MedGenome's various research projects comprise around 65 percent of the firm's overall business, with clinical testing representing 35 percent. The firm has developed clinical tests for rare disease and cancer, and is also licensed to run Natera's noninvasive prenatal test.

Rare disease testing makes up the majority of the clinical tests it runs, Santhosh said, and includes everything from single-gene tests up to exome sequencing. The genetic testing market in India is all self-pay, Santhosh said, so the firm has to keep costs low. He said single-gene tests cost around $50 while exome sequencing is around $300, while its liquid biopsy and NIPT assays run between $300 and $350.

"India has a big burden" of inherited disease, he said. "These new technologies have been a big boon in trying to solve those cases." And, as sequencing costs have dropped, diagnostic exome sequencing has picked up. Over the last three years, he said the firm has conducted around 10,000 exome sequencing tests for children with rare, inherited disease, and has a diagnostic rate of between 35 and 40 percent.

Last year, the firm launched a liquid biopsy assay, OncoTrack, which focuses on hotspots in four genes — EGFR, KRAS, NRAS, and BRAF. The test is aimed at patients with colorectal cancer, lung cancer, and melanoma, and focuses on identifying mutations that point to available targeted therapies.

Santhosh noted that the Indian genomic testing market is challenging due to the lack of health insurance as well as the lack of professional societies that help push for standardized protocols. Only around 5 percent to 10 percent of the Indian population has any form of health insurance, Santhosh said. And while there is a push to expand access to healthcare, the focus is on covering in-patient care and not diagnostic testing.

In addition, Santhosh said, there are no organizations like the American College of Medical Genetics and Genomics that can evaluate genomic technology and make recommendations. Such professional societies can help to encourage testing standardization, and once they issue a recommendation about a test or technology, organizations across the country eventually move to conform to those guidelines, making specific tests more uniform. "But, that's not there in India," he said, which also adds to the challenges and means that the firm also focuses a lot on education.

The clinical genomics market in India is still in an early stage of adoption. Other companies in the space include a Cancer Genetics subsidiary that offers NGS gene panels for several tumor types; Mumbai-based Positive Bioscience, which offers both NGS testing for healthy individuals as well as oncology testing from Myriad Genetics; Supratech Micropath, a reference and diagnostic laboratory that began expanding into the NGS space a few years ago; and New Delhi-based Lifecode Technologies, whose offerings include exome testing for undiagnosed inherited diseases.

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