

Circulogene Theranostics Taps Station X to Power Genomic Data Interpretation for Non-Invasive Liquid Biopsy Services

When clinicians count on you to deliver information to support critical patient care decisions, the ability to quickly generate reliable insights is essential

For clinicians treating people with cancer, up-to-date actionable information is vital to monitoring a patient's progress and improving care outcomes. Birmingham, Alabama-based Circulogene Theranostics is on a mission to improve how clinical oncologists monitor and treat cancer using genomic information.

Circulogene's proprietary method provides a simple, streamlined, and robust workflow optimized for cell-free DNA enrichment and recovery from a droplet of plasma or serum as an alternative to low-quantity, poor quality DNA from challenging tissue biopsy samples or other liquid biopsy companies. It is the first, non-invasive method that allows accurate next generation sequencing-based (NGS) genomic analyses directly from droplet volumes of blood. With a simple finger stick, Circulogene's patented technology utilizes NGS to monitor known tumor mutations (approximately 3,000) in 50 established cancer-associated genes and further provides information on current FDA-approved treatment options. The company learned about GenePool® from Station X when it started looking for an automated reporting platform that could also handle large genomic datasets.

"We needed a solution that would allow us to streamline our workflow from sample-in to report-out and help us aggregate the large amount of data we are working with. Station X helps this process by rapidly integrating insights that we can use to create intuitive reports that clinicians can consult to help guide treatment options for their patients," said Dr. Chen-Hsiung Yeh, Chief Scientific Officer at Circulogene.

GenePool is a secure software-as-a-service enterprise genome management system that allows organizations to access, integrate, distribute and manage their clinical genomic information more efficiently and effectively. GenePool is pre-loaded with standard clinical reporting capabilities for incidental findings and tumor profiling, but its flexibility means organizations like Circulogene can customize GenePool for use with their proprietary gene or variant testing panels and annotations. GenePool also provides a convenient and dynamic way to securely store patient data for updated reporting, ongoing monitoring and for investigating the aggregated information.



Mike Mullen
Co-founder and CEO at
Circulogene Theranostics

"GenePool is helping enable our vision of establishing our services as a new standard in the fight against cancer care."



Actionable Insights

Today, it is recognized that cancers are diseases of the genome and that truly understanding them begins with the identification of abnormal biomarkers that can be linked to the disease. Circulogene intends to support oncologists by providing real-time molecular information on a patient's specific cancer and connecting them with actionable information on a particular mutation, potential targeted therapies, or ongoing clinical trials.

"Advances in genomic technology have resulted in large biological datasets that continue to increase in size and actionability on a daily basis. Today, oncologists need to know what mutations have been found to help treat their patient's specific disease. In addition, they want to ask questions like, has anyone ever seen this mutation pattern before? Are there any treatments that target this specific biomarker? Are there clinical trials for which this patient might be a match?," stressed Yeh.

GenePool provides Circulogene an up-to-date knowledge platform that allows them to aggregate genetic, biochemical, and clinical information from public and proprietary databases to further define molecular subtypes and identify approaches to cancer care that they could use in the development of reports for their clinician customers. Through GenePool, Circulogene can develop custom reports supported by the comprehensive analysis of rich and ever-growing content libraries such as The Cancer Genome Atlas (TCGA), ClinVar, dbSNP, FDA Biomarkers, PharmaADME, and many others.

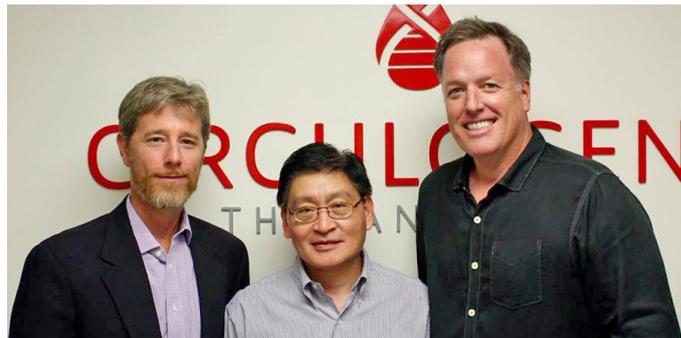
"The power of our unique blood drop-based test really shines when we can quickly take that data and query it against the large pool of aggregated up-to-date datasets that are integrated within GenePool," said John Athanasuleas, a Team Lead at Circulogene. "With the support of Station X, we know that the reports we create will represent the most current information available and offer insights that have the potential to make a huge impact on patient care."

Rapid Implementation

Station X has designed GenePool as a cloud-based service that can be rapidly deployed and yet easily scales up to meet the growing demands of a successful testing laboratory.

"It was important to us that our data analysis pipeline didn't require a huge capital investment in technology or assembling a team of in-house bioinformaticians to manage," said Scott Rezek, Chief Operating Officer at Circulogene. "Deployment has not been a barrier to entry for us. Integrating our data into GenePool has definitely been one of the smoothest parts of our workflow."

GenePool was designed in collaboration with experts in biomarker discovery, and includes as standard the key statistical analyses they use. Although sophisticated analysis capabilities are integrated into GenePool, it is approachable, uncluttered and intuitive to use. Whether the project involves cohorts of genomes, exomes, targeted sequences or transcriptomes, one



Circulogene leadership team. From left, Scott Rezek, Chief Operating Officer, Dr. Chen-Hsiung Yeh, Chief Scientific Officer and Mike Mullen, President and Chief Executive Officer

to thousands of samples can be compared in just seconds, identifying key genes and variants associated with outcomes.

"We have found that a single person can process hundreds of samples using GenePool, which frees up our resources to focus on new test development and supporting our clinician customers," continued Rezek.

Through a flexible API, GenePool is able to integrate with existing LIMS systems and leading third-party data storage and management platforms including Amazon Web Services, DNAnexus, Google Cloud Platform, Illumina's BaseSpace, Microsoft Azure and Seven Bridges Genomics. End-to-end security and privacy provides encryption of data at rest and in motion. Full auditing and system review by third-party security experts ensure that data are never compromised.

"As a CLIA lab, data security is vital. Partnering with Station X removes that burden from our team and places the management of this critical function into the hands of experts in creating secure systems for managing data," said Athanasuleas.

Bright Future

Sequencing-based liquid biopsy tests have the potential to become a gold standard test for cancer management in the era of precision medicine. Circulogene is already anticipating significant growth in the number of tests they will process this year and are exploring the expansion of the company's testing portfolio.

"We are focused on providing the most relevant and actionable data to our customers. With the support of Station X and GenePool, we are confident that we can continue to rely on their bioinformatics expertise to understand mutations that drive cancer and hopefully can impact the treatment decisions to produce a favorable outcome," said Mullen.

For more information on GenePool, contact Station X at info@stationxinc.com.