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GENETIC TESTING

> DR. SURYA SINGH, CEO

Actionable Genomic Insights for Successful Clinical Trials

InformedDNA



Life Sciences Review



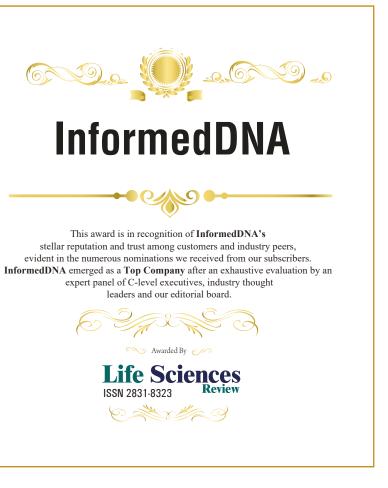






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COVER STORY

InformedDNA

Actionable Genomic Insights for Successful Clinical Trials

> linical trial criteria and protocols have undergone a significant transformation, with genomics heralding a new era of precision and efficacy. For trials that focus on rare disorders in subpopulations, targeting specific molecular profiles is an integral part of their parameters.

Biotech and pharma companies need to partner with genetics experts who can accurately interpret data, ensure participants meet clinical trial criteria and improve trial efficacy.

When it comes to advancing precision medicine, InformedDNA has become a vital partner. It identifies eligible patients through genetic testing, boosts enrollment rates and provides counseling to patients to increase retention rates.

By unlocking genomic insights, the firm provides tech-forward solutions for life sciences companies. Its offerings include genetic counseling services, clinical trial recruitment and genetic testing utilization management. As a precision health company, InformedDNA's mission is to ingrain genetic testing data into critical decision-making to make a significant and immediate impact on clinical trials.

"Our work is marked by exceptionally high integrity standards, enabling us to enhance the volume and speed of service delivery," says Dr. Surya Singh, CEO.

Honing in on Precise Molecular Profiles

Drawing on its legacy, InformedDNA leverages its proven ability to adapt to the evolving genomics landscape, which leads to enhanced patient outcomes. David Patrick Nixon, executive chairman / director and Rebecca Sutphen, MD, FACMGG, chief medical officer, founded it in 2007 with the OUR WORK IS MARKED BY EXCEPTIONALLY HIGH INTEGRITY STANDARDS, ENABLING US TO ENHANCE THE VOLUME AND SPEED OF SERVICE DELIVERY DR. SURYA SINGH, CEO Life Sciences Review TOP 10 GENETIC TESTING SERVICES PROVIDERS - 2024



aim of extending genetic counseling access to a wider population. It subsequently collaborated with payors to write medical policies for genetic testing and supported life sciences companies in clinical trials, particularly in oncology and ophthalmology.

Today, InformedDNA supports numerous smaller biotech and pharmaceutical companies that spearhead the development of pharmaceutical drugs for rare disorders. Their strategy is to bring in InformedDNA's team of experienced genetics experts early on to accurately interpret test results, enroll the right patients and optimize the overall process.

Reviewing molecular profiles requires specialized genetic training and expertise-attributes that InformedDNA excels in. Failure to do so can lead to inaccurate patient enrollment. A mismatch between genotype and phenotype correlation poses a crucial challenge, resulting in incorrect trial results. Patients identified by a provider or enrollment site are referred to InformedDNA. It thoroughly analyzes patients' genetic profiles, as well as personal and family medical history, to determine whether they meet trial inclusion or exclusion criteria.

A case study reports a 38 percent surge in positivity rates, demonstrating the approach's efficacy. This refers to the increase in patients possessing molecular profiles that meet the trial inclusion criteria. Comparatively, 15 times more patients received counseling, thanks to improved accessibility made possible by InformedDNA. This enabled them to overcome challenges in scheduling appointments with genetic counselors within the clinical trials' limited timeframe.

WE SUBSCRIBE TO THE THINKING THAT IF CUSTOMERS **AREN'T SUCCESSFUL, THEN WE ARE ALSO NOT**

Its involvement in patient recruitment and counseling services has led to a 200 percent increase in referral volume. The team also approaches patients from its existing database to identify suitable candidates for a clinical trial.

InformedDNA has expedited patient enrollment and recruitment rates in over 35 clinical trials it has supported. Many patients drop out during recruitment for various reasons, including reluctance to undergo tests or enroll in trials. In such cases, having an expert clinician on board to interact with them during this crucial window helps in retention-a feat InformedDNA achieves effortlessly. This has led to an unprecedented rise in accrual rates regarding the number of patients agreeing to genetic testing and the timeframe in which they agree.

Through a team of 55 genetic counselors, the company has established specialized practice groups for various medical specialties. Genetic counselors in dedicated teams focus on areas such as oncology, ophthalmology and neurodegenerative conditions, enabling the company to provide highly tailored support to clinical trials across different medical domains. For instance, when supporting a clinical trial for frontotemporal dementia, InformedDNA guides counselors on neurodegenerative conditions instead of

relying on generalist counselors. Ninety-five percent of patients who undergo counseling and are found to be eligible for a trial agree to proceed with the enrollment process.

InformedDNA is broadening its horizons to deliver innovative services by offering its clients post-market support. After the trial is approved and the therapy is commercialized, it provides supportive programs to identify candidates for precision medicine therapies that target specific genetically defined subpopulations. As part of the sponsored genetic testing program, InformedDNA encourages specialists involved in the diagnostic process to conduct genetic testing on patients with the drug manufacturer's or sponsor's support. These specialists then refer the patients to InformedDNA for counseling and evaluation to determine the suitability of a particular precision medicine therapy. While it does offer test ordering services for diagnostics, it does not directly prescribe precision medicine therapies. Since the team works closely with payors, it is also consulted when developing coverage policies.



Turning the Next Page

Service marked by exceptionally high integrity standards is the hallmark of InformedDNA, opening doors to enhanced guality and speed of service

services.

success.

delivery. The team walks the extra mile, adjudicating the results of the genetic tests conducted by other reputed labs. This service is offered through CLIAcertified and CAP-accredited labs that it has vetted and subcontracted. Most of the time, the adjudication reveals that the staff involved in the clinical trial have misinterpreted the test results. The firm's experts analyze the results, ensure the lab report corresponds to the assigned phenotype from a clinical perspective and verify the accuracy of genotype-phenotype matches. The clinical trial staff is informed of all data collected and engaged in testing to determine a patient's gualification to participate in a clinical trial. InformedDNA is driving a tech transformation in the industry. It is actively adopting the latest technology and tools, like a unified rules engine and content management system, allowing for more efficient data processing and analysis across all parts of the client's business and patient streams. The company has also elevated the digital sophistication of patient communications beyond basic PDF reports, enhancing the quality and delivery of

Accelerating to New Heights

InformedDNA is characterized by its positive company culture centered on its shared values of innovation, care, belonging and collaboration. It aggressively rethinks industry solutions and provides transformative life sciences offerings built on curiosity, creativity and thoughtful risk-taking. Empathetic toward employees, it supports and encourages them to dedicate time and effort to address client needs and foster a collaborative work culture that empowers each other to walk toward shared

"We subscribe to the thinking that if customers aren't successful, then we are also not," says Singh. "It's not a zero-sum game where we need to succeed at the expense of our clients. Rather, we succeed when our clients succeed."

InformedDNA's value proposition to clients is patient care. A testament to this approach is that it garnered extremely high net promoter scores and excellent patient satisfaction rates.

Envisioning a future where healthcare is genuinely personalized, it considers patients' individual needs and details like location and grants uniform treatment options. Patients can get universal access to optimal health journeys without being hindered by costs or constraints. InformedDNA's team of genetic counselors and genomics clinicians create a reality where the application of genomic insights is fundamentally transformed for enhanced patient care and clinical trial success.