Simranjit Singh – CEO, Guardant Health AMEA

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Simranjit Singh highlights Guardant Health's role in the global precision oncology landscape and how the company leverages its proprietary blood tests, vast data sets, and advanced analytics across the huge AMEA region. Singh also touches on the significance of a recent US FDA approval for its comprehensive liquid biopsy and talks growth plans, target markets, and adoption challenges.

What was your career trajectory up until taking on this role and how do you draw on it today?

I started off in healthcare management consulting and eventually headed up Frost & Sullivan's Asia Pacific healthcare team, with a particular focus on biopharma, medical devices, diagnostics and the CRO industry. I spent around six years at Frost & Sullivan before joining Quintiles, previously one of my biggest customers and the largest global Contract Research Organisation (CRO).

The then CEO of Quintiles brought me in to head up a newly formed Strategy Group aimed at growing the company's Asia presence. At the time in 2010, the company made around USD 450 million in revenues, and my role was to more than double this to USD one billion by 2015, which we were able to execute a year early. This transformation process exposed me to the Asia Pacific region, with a restructuring of the business in Japan, a dual brand strategy in China, operational expansion in Taiwan and Korea, and the creation of a back office Centre of Excellence in India.

After that, I helped launch the global business unit for medical devices and diagnostics within Quintiles, the first time that the company had looked beyond biopharma. This brought a lot of new technologies to my attention, including liquid biopsies as we were working with many of Guardant's competitors on regional clinical trials. Serendipitously I met the founders of Guardant Health who convinced me to come and work for them and the rest is history!

Could you introduce Guardant Health Asia, Middle East and Africa (AMEA) and its positioning?

Guardant Health is a leading precision oncology company focused on helping conquer cancer globally through the use of its proprietary blood tests, vast data sets and advanced analytics. The Guardant Health AMEA operations are a 50/50 joint venture between Guardant Health Inc. and SoftBank established in 2018 with an initial investment of USD 50 million from both parties. I was brought in to head up operations in the region as CEO, based in Singapore. From there, we established a regional headquarters here in Singapore and established our lab and office in Japan.

AMEA is an enormous region to cover, what mandate were you given when taking on this role?

I feel that Guardant Health has been very innovative in the creation of this structure and to do it as a joint venture. Most other diagnostic companies see AMEA as almost an afterthought, with less than 10 percent of revenues coming from outside of Europe and the US. However, Guardant's founders, along with SoftBank, understand the heterogeneity of the region and the need for a different focus, localisation, and becoming embedded here.

Asia Pacific has the largest cancer burden and highest cancer mortality rates in the world, so the need is there, meaning there is an enormous opportunity for growth. A dedicated regional strategy and the flexibility to localise solutions is, therefore, key to success.

Last year, Guardant Health's companion diagnostic, the Guardant360® CDx test became the first comprehensive liquid biopsy to receive US FDA approval. How significant are FDA approvals for Guardant Health and how are you looking to leverage them in your managed markets?

The FDA approvals are a huge milestone for the company. We were awarded the first liquid biopsy FDA approval for comprehensive tumour profiling across all solid tumours in August 2020. This gives us a stamp of approval and provides credibility for the clinical utility of the test. We have already amassed a large amount of scientific and clinical evidence, with over 200 peer-reviewed publications and numerous clinical studies on the clinical utility of the test. This approval verifies and validates the research and evidence that has been amassed and gives confidence to oncologists to use the test to guide treatment decisions.

All of this represents a paradigm shift in the concept that traditional invasive tissue biopsies are the gold standard. With the dogma that we should do no harm to patients in mind, it makes sense to first use a non-invasive test before moving to a more invasive tissue biopsy. We are seeing more physicians now thinking about liquid biopsies upfront as an easier, safer, faster, and more effective tool to make treatment decisions; a trend which our FDA approvals have helped bolster.

Beyond the FDA approval, we have begun to work very closely with biopharma companies who have also realised that a liquid biopsy can help them to stratify the patient cohorts that will benefit the most from their drugs. With the advent of precision medicine and precision oncology, this has become a large part of biopharma companies' considerations; looking at specific biomarkers to provide maximum patient benefit. Guardant Health has a set of companion diagnostics, and we recently received approval for our companion diagnostic for Amgen's new KRAS treatment. As KRAS was previously considered to be an undruggable target, this is a big breakthrough for patients.

What is the timeline in terms of bringing these tests to the Asian market?

Our products are already being used in Asia. Guardant Health is in a unique position because our technology is so novel and innovative that many of the regulatory pathways are not yet established. In the US, there is a specific next generation sequencing (NGS) in-vitro diagnostics (IVD) pathway. NGS requires a centralised model, unlike traditional IVD. Most Asian markets see the FDA as a credible regulatory agency, and therefore despite not having an approval pathway for them, several countries have placed their trust in the FDA approval and brought the tests to their home markets.

Of course, this access comes with restrictions, but they are currently being used while approval pathways are created in parallel. For example, Japan has been an early adopter, creating a specific pathway for NGS genomic panels. Interestingly, Japan's regulatory body, PMDA, has defined the

test as a medical device software as it is a combination of a number of different technologies, from biochemistry to sequencing, bioinformatics, medical device, and software. We have recently submitted Guardant360 CDx for regulatory approval to the PMDA and do hope for an expedited approval.

Regulators are in a difficult position and still coming to understand how to define these new technologies. Greater alignment with the US does seem to be the most beneficial way forward and we will increasingly see greater pathway harmonisation across regions.

Because of the regulatory sophistication needed to bring these tests forward, presumably Guardant Health is looking to Asia's most developed markets?

At the end of the day, we are still a start-up – maybe not a traditional one – but a start-up nonetheless. Therefore, ultimately, we are limited by resources and bandwidth. The company has focused on where the largest burden of disease is and where we can make the biggest impact. Japan is a huge market with a million new cancer cases per year, which is coupled with good government support, a regulatory pathway, reimbursement and a lot of support for the use of comprehensive genomic profiling for treatment selection for advanced cancer patients.

Guardant Health is part of a highly promising public private partnership in Japan, where there is government support for genomic testing for all advanced cancer patients. The Guardant360 test is one of the liquid biopsy platforms for advanced cancer patients to be screened to get appropriate therapies. 20 biopharma companies are also participating, along with the government, hospitals, and us as a diagnostics provider. Funding is provided by the biopharma companies themselves and is being matched by the government. This provides access and we think these kinds of programmes will become the norm moving forward in terms of expanding precision oncology and making it accessible for the masses.

The public private partnership structure and framework that Japan has created works because biopharma companies have the incentive to accelerate new drug development and create study arms for patients with specific biomarkers. This also creates much faster access. Patients still benefit because if they do not get enrolled to the study, they still get standard of care therapy. This is a win-win situation for all parties.

With liquid biopsy technology being touted as less invasive and having a shorter turnaround time than traditional tissue biopsies; could COVID-19 and the fact that patients can do these tests at home or in outpatient clinics be an inflection point for their uptake?

In 2020/21, we have seen a swift pivot to new technologies. Lockdowns occurred very abruptly in many markets with very little time to prepare and access to doctors and treatments were restricted. As cancer patients are one of the most vulnerable groups to COVID-19, with many being immunosuppressed, they were not able to schedule doctor visits or tissue biopsies. Therefore, many who wanted to undergo treatment were not able to do so due to the lack of a proper diagnosis.

Seeing this and, as our test is a simple blood draw which can be done anywhere, we employed mobile phlebotomists to go to patients' homes. Many more doctors and oncologists became open to these tools due to the need for an effective diagnostic alternative. We ran almost 20 webinars last year with over 600 oncologists in attendance – numbers that were unheard of in previous years – and liquid biopsies are now a major part of their toolbox in ensuring patients continue to be treated.

What are the main stumbling blocks on the road towards greater adoption of liquid biopsies? Is it a lack of regulatory pathways, costs, education, or something else?

The creation of regulatory pathways remains our number one priority. We hope that there will be harmonisation, but we also understand that this will be difficult due to the different jurisdictions and interpretations. Ultimately, the creation of regulatory pathways will be crucial to standardising the technologies that enter the market and making sure that only the most validated, effective, and scientifically credible tests reach the patients.

The second piece is education. Oncologists' experience levels across the region vary widely, with huge knowledge and capability gaps between professionals in the advanced and the emerging Asian markets. There is a need for them to be educated that comprehensive genomic profiling is a must for advanced cancer patients. Personally, I feel that it is almost unethical that genomic profiling is not being provided for many of these patients. At its core, cancer is a genomic disease and with so many biomarkers, genomic alterations, and mutations driving it. Without comprehensive genomic profiling, effective therapies may be missed. Once the importance of comprehensive genomic profiling is established, there then needs to be a focus on the different

modalities – whether tissue or liquid biopsies – understanding the benefits and shortcomings of both, and how faster, safer, and accurate treatment decisions can be made.

Thirdly, access to medicines is key. Ultimately, there is no point doing the genomic profiling if the appropriate medicine or therapy is inaccessible. This ties into the question of value-based reimbursement; moving away from a narrow focus on costs alone and ensuring that money is only spent on therapies which have the potential to be effective for patients.

Why does it make sense to base Guardant Health's Asian expansion story from Singapore?

Singapore has a very strong business environment, with ease of doing business enshrined at the heart of how the country operates. That allows us to set up very quickly and create partnerships. Also, given the high level of trust in Singapore's geopolitical standing among other countries in the region, we can do business elsewhere easily. From a logistical standpoint, Singapore's accessibility and connections are also important. Post-COVID, when international travel resumes, this proximity to our customers throughout the region will gain in significance.

Moreover, the Singapore government provides a lot of incentives and focus on R&D, allowing us to engage in research partnerships and clinical studies here. The country's world-class standards and credibility help Guardant Health to build up its base of clinical evidence.

The other important part of the Singapore ecosystem is talent. With many biopharma companies' regional headquarters, plenty of top-class research institutes, and several cancer consortiums for both Singapore and APAC, Singapore is a regional hub for talent.

With the company's new investments in Japan and its background as a joint venture with a Japanese bank, will Japan supersede Singapore as Guardant Health's regional hub?

We do not have to choose between Singapore or Japan, both are important. The involvement of SoftBank has provided us with a network and support to grow our operations in Japan, but the country is also important as a biopharma development hub with government support for genomics. Because of this, we built our first lab outside of the US in Japan where, with the increased adoption of genomic testing, there is going to be a greater need for tests like ours.

However, our next nexus of growth will probably be China; home to 50 percent of the region's cancer patients and with the highest levels of new incidences of cancer. We are now strategizing around collaborations and partnerships, both with biopharma and clinicians there – so stay tuned!

China represents a big opportunity but also a big challenge, with homegrown companies having a significant advantage on foreign market entrants like Guardant Health.

China is not without its challenges, whether in terms of regulation, geopolitics, technology, or IP, but it is a market that it impossible to ignore. More importantly, there is a huge unmet patient need there. Local biopharma players are developing drugs but there is a need for genomic profiling to select the right patient cohorts for those drugs. While navigating the challenges that exist will be tricky, we believe that with good collaboration with a suitable local partner, Guardant Health will be able to overcome the challenges.

Given the size and diversity of the AMEA region, what has been your experience of trying to build a unified team and company culture?

We work towards our company values with a strong focus on patient centricity. At Guardant Health, we believe that we need to treat the patient as a family member and do what's best for them. There is also an emphasis on teamwork and collaboration as well as integrity; building up stakeholder trust.

Another key point is diversity in the team; we have walked the talk and truly have a racially and gender diverse team and leadership. Diverse thinking can help us drive our strategy. As a start-up, we need to be nimble and think outside of the box, which our diversity allows us to do.

What advice would you give to young talents starting out in the industry?

There is no better place to be than the biomedical industry right now. COVID-19 has put us at the front and centre of people's minds, but we are never going to be a sunrise or sunset industry; we will always be essential.

Young people starting out in their careers need to be passionate and driven to make an impact for patients. Patients are dependent on our innovations. Everything needs to be done with them in

mind to ensure the best outcomes. Of course, there is a huge growth opportunity in healthcare, but making an impact for patients should always remain the priority.

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