Precision diagnostics and digital convergence that drive the clinical diagnostics market

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Healthcare is rapidly becoming patient-centric with a focus on outcomes and value. This has provided opportunities for clinical diagnostics players to advance their instruments, assays and informatics capabilities to address unmet clinical needs and foster their precision diagnostics portfolio. The advances in next-generation sequencing (NGS)-based companion diagnostics (CDx) and liquid biopsy are helping address precision medicine approaches toward diseases such as cancer. Another paradigm that is setting the stage in the diagnostics industry is linking automation with digital technologies to improve efficiency and productivity, such as leveraging artificial intelligence (AI) to improve workflow, accuracy and efficiency.

The blood analysis for circulating tumor cells (CTCs) or circulating tumor deoxyribonucleic acids (ctDNA) has opened new avenues for **cancer diagnostics,** including early detection of tumors, improved risk assessment and staging. This reveals the relapse and monitors the tumor evolution in the context of cancer therapies. The approval of a companion diagnostic that uses a **liquid biopsy and NGS** has marked a new era for mutation testing. The United States Food and Drug Administration approved more than 10 breakthrough devices in 2021. The designations boost the development of the tests through clinical trials as a **companion diagnostic and multi-cancer diagnostic**, including products from leading companies such as Natera, Bluestar Genomics, and Inivata.

Apart from oncology, the advancement of ultrasensitive blood-based protein detection technology is enabling simple, non-invasive, and accurate diagnostic solution for neurodegenerative diseases such as Alzheimer's disease, Parkinson's, and Down Syndrome. Liquid biopsy will greatly facilitate **early identification and staging of the disease,** significantly reducing the time and cost burden. Non-invasive prenatal testing to detect fetal aneuploidies in pregnant women is another emergent area.

The global market for liquid biopsy was estimated to be in the range of USD 3.5 billion to 4 billion in 2020. While the US holds the largest market share, the GCC maintains a strong focus on precision medicine and is expected to show a higher growth rate over the next five years. Within the GCC regions, the Kingdom of Saudi Arabia (KSA), United Arab Emirates (UAE) and Kuwait represent approximately 85 % of the incident cancer patients. Based on The International Agency for Research on Cancer, Globocan database, this number is expected to have a growth rate of 5 % from 2020-2025 within the GCC region. This is almost 1.5-2 times the growth rates of the western world. Addressing the gaps in the cancer care continuum and implementing precision diagnostics can go a long way in improving patient care.

Frost & Sullivan has identified the top opportunities within the precision diagnostics sector:

1. **Minimal or molecular residual disease (MRD) monitoring:** This represents a new frontier for the application of liquid biopsy, which is challenged by low concentrations of CTCs and ctDNA in blood samples. CTC detection during the primary diagnosis of cancer predicts an unfavorable prognosis, further **enabling cancer surveillance, risk stratification and management** strategies beyond the current approaches to tumor staging. Similarly, monitoring CTCs and cfNA during post-surgical follow-up assessments can enable the earlier detection of disease relapse than is possible with current radiological imaging procedures. MRD at early stages represents significant clinical application for liquid biopsy-based precision diagnostics, followed by cancer diagnosis and treatment selection and monitoring (metastatic setting).

2. **Pan-cancer Screening:** There has been intense interest from developers as this involves **evaluating the frequently mutated genes and other genomic abnormalities** common to many different cancers, regardless of tumor origin. Ongoing results from Guardant's CancerSEEK or GRAIL's Galleri suggest that the use of ctDNA can detect cancer with specificities >99 % , while sensitivity is cancer- and stage-dependent. The pan-cancer assays using liquid biopsy are useful for screening cancer patients in affected populations and are suitable in regular examinations for early detection.

3. **Non-invasive Prenatal Testing:** The cell-free fetal DNA (cffDNA) released by apoptotic trophoblast cells within the fetal compartment of the placenta can be used for nucleic acid-based, non-invasive prenatal testing (NIPT). NGS-based methods can also be applied to study the epigenome of cfNAs and characterize cfRNAs. The application of NIPT is growing rapidly, particularly for pregnancies with high risk or complications. It provides parents and clinicians with a safe and simple method for the **early detection and management of expected fetal disorders before birth.** The utility of testing extends from determining the risk of the most common chromosome aneuploidies, including Down Syndrome, Edwards Syndrome, and Patau Syndrome, as well as chromosome microdeletions and the predicted sex.

4. **Artificial intelligence and machine learning for predictive analysis:** The data from liquid biopsy testing using NGS or other techniques usually arises from the multiplexed measurements of different biomarkers that define robust signatures for specific disease states. AI and machine learning algorithms can simultaneously evaluate the effects of many biomarkers and discover higher-order interactions among biomarkers that would not be possible to design manually. The integration of these techniques and multi-omics, including genomics, epigenomics, transcriptomics, proteomics, and metabolomics, provides unprecedented opportunities to understand the underlying mechanism of tumor occurrence and early detection. Several companies **integrated AI solutions into their informatics pipeline,** including data pre-processing, sequence analysis, and supporting patient stratification and outcomes prediction.

Within the GCC countries, early cancer detection programs have been recognized as a much-needed priority in the current and future strategic planning of healthcare policies and are a priority for healthcare providers in the region. The most common cancers of public health importance and that are receptive to early detection include breast, colorectal, cervical and oral cavity cancers. According to WHO, the cancer incidence rate in the UAE, among those aged between 20 and 49, was more than 37 %; it was more than 39 % among this age group in KSA. Compared to other countries such as the US, where the cancer rate among this age group was less than 9 %, the GCC region is demanding measures to address the cancer pandemic.

The Department of Health Abu Dhabi (DOH) initiated screening programs for colorectal, breast and cervical cancers in 2009. The Dubai Health Authority (DHA) introduced breast, cervical and colon cancer screening in 2014. In the UAE, lung cancer was the third-leading cause of death due to cancer in 2017, with about 80 % of the patients diagnosed at a late stage, rendering treatment less effective in improving survival outcomes. In 2017, lung cancer screening was recommended by DOH. In the same year, the Cancer Patient Support Program (BASMAH) initiative was launched, covering the insurance scheme for screening and treating breast, colorectal and cervical cancers.

With the expected cancer burden and increasing cost of treatment, **creating and implementing cost-reduction strategies is important.** Within the UAE, guidelines from authorities include recommendations to regulate the use of imaging, CT and MRI, which have been overused in cases with little evidence to support the need. Molecular genetic testing for hematological cancers and solid tumors, as well as NGS, is highly utilized for cancer care. According to the Emirates Oncology Society, one of the limiting factors is the extended time for obtaining the results of essential tests. Most tests are done outside UAE due to a lack of specialized laboratories, leading to a timeline of up to 4-6 weeks and delays in receiving results. Precision diagnostics leveraging liquid biopsy could provide fast, efficient and reliable ways to address the situation. There is already some activity within the region. Organizations such as Thumbay Research Institute for Precision Medicine at the Gulf Medical University in Ajman provide fourth-generation sequencing and facilitate liquid biopsy. Similarly, OncoDNA, a Belgian company specialized in liquid biopsy, has partnered with International Medical Center in Jeddah.

Participants and technology developers **must design and demonstrate clinical validity** in prospective cohort studies (for use in the intended population). Clinical validity studies ensure private payor market access. Understanding reimbursements, using the coding formula, and **leveraging real-world evidence in combination with solid trial results can** pinpoint the best test for reimbursement. Multi-cancer tests, as opposed to single-gene testing, will be in demand as the market gains momentum. It is important to justify the price and advantage of using such multi-cancer panel tests in laboratories.

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