OneCell Diagnostics
OncoIndx
NexGen Sequencing

When Precision Meets Decision.

Personalising genomics for cancer treatment.

Meeting stringent and latest global standards.

AI / ML (iCore) enabled dynamic data analysis.

Actionable insights for faster decision making

Maximise treatment success and patient benefits

BACKGROUND

The intersection of innovation and knowledge-sharing has yielded noteworthy advancements in cancer treatment and management via diagnostic and therapeutic interventions. The availability of high-quality services, characterized by accuracy, integrity, and timely transmission of information, is challenging but has always been paramount for the equitable care of cancer patients. OneCell Diagnostics has developed a comprehensive genomic profiling solution called OncoIndx. This solution utilizes next-generation sequencing (NGS) technology to provide targeted gene panel analysis, extracting actionable information for cancer patients. OncoIndx is a product of the collaboration between cell science and data sciences. It aims to make cancer testing accessible through high-throughput genomic testing, thereby improving cancer treatment and enhancing patient outcomes.

CHALLENGES

Challenges in cancer patient monitoring and surveillance

Cancer and cancer patient monitoring and surveillance is huge problems and unmet needs. There are 1.7 to 1.8 million cancer patients in the USA and 1.4-1.5 million cancer patients are added every year in India. Almost 7-8 lakh patients die because of cancer every year. It means that every minute, one dies as a result of cancer and 80-85% of those deaths are attributed to cancer recurrence. Cancer could return in 6 months to 5 years. Unfortunately, the standard of care is essentially post-intervention, or "wait and watch." If some symptoms appear, we conduct image studies such as CT, MRI, and PET, but these are insufficient for early detection of metastasis of recurrences. As a result, cancer patient monitoring and surveillance are a massive challenge and an unmet need. Hence the fear of recurrence is a hanging sword.

"Unfortunately, for complex diseases like cancer one shoe does not fit all, we need personalized treatment and care"

The field of precision oncology aims to identify the unique genetic and molecular characteristics of a patient's cancer and use that information to tailor personalized treatments that are more effective and have fewer side effects. This approach is in contrast to traditional cancer treatments that are based on a one-size-fits-all approach.

Comprehensive biomarker analysis is a critical component of precision oncology because it allows oncologists to identify specific genetic mutations and other molecular characteristics and signatures that are unique to a patient's cancer. By analyzing a wide range of biomarkers, oncologists can gain a more complete understanding of the biology of a patient's cancer and make more informed decisions about treatment options.

"Precision oncology with comprehensive biomarker analysis is the future of cancer care, and liquid biopsies are a critical tool in achieving the goal"

Patient tumor samples, however, may not accurately represent the entire cancer's genetic makeup, which can lead to insufficient treatment decisions. That's where liquid biopsies come in. Liquid biopsies are non-invasive tests that analyze a patient's blood, and other bodily fluids to detect the presence of cancer biomarkers. These tests can provide a more comprehensive and accurate picture of a patient's cancer because they analyze genetic material that is shed from the cancer cells into the bloodstream. It provides a more comprehensive and accurate picture of a patient's cancer, allowing oncologists to make more informed decisions about treatment options and improve patient outcomes.

Delayed cancer diagnosis severely limits treatment options

A delayed cancer diagnosis is when a person's cancer is not detected until it has progressed to a later stage. Also, diagnostic tests are more likely to fail to identify relevant driver genes when cancer has already metastasized. The earlier cancer is diagnosed, the more treatment options are available, and the better the chances of a positive outcome for the patient.

A large majority of the cancer mortality burden can be prevented simply by early detection. Delayed diagnosis of the disease frequently results in treatment failure. Studies have reported a correlation between the stage-specific diagnosis of breast cancer and the outcome in different hospitals across Asia, Africa, and Latin America.

"Almost 30-98% of breast cancer diagnoses in Asian and African countries occur beyond Stage 3 and Stage 4. A late diagnosis can severely limit available treatment options for patients"

Late-stage cancer can also limit the ability of the patient to participate in clinical trials for experimental treatments, which are often conducted in the early stages of cancer. Patients who participate in clinical trials have access to new and potentially life-saving treatments that may not be available through standard treatment options. Hence, developing diagnostic tests that can identify alternative cancer-related genes that can target both the early and advanced stages of the disease is becoming important.

OUR SOLUTIONS

OneCell Diagnostics acknowledges the difficulties associated with managing intricate cancer cases and has developed a next-generation sequencing (NGS) test that is augmented with artificial intelligence (AI) utilizing up-to-date resources of published clinical studies. This test is designed to aid in identifying the most advantageous therapeutic options leading to treatment-relevant actionable information for improved patient care options.

What is OncoIndx?

OncoIndx is a proprietary first-in-class comprehensive genomics profiling solution that includes over 1000 cancer-relevant genes of known alterations that significantly impact cancer initiation and growth. Its extensive design can identify even rare mutations, which can help identify new therapeutic targets to develop the most informed personalized treatment plans.

The OncoIndx test solution provides faster, more affordable, and 98-100% coverage of all included genes that can inform treatment decisions. Moreover, OncoIndx offers an intuitive digital interface that makes it easier to interpret and comprehend complex cancer genomics.

Where is OncoIndx needed?

OncoIndx has the potential to significantly improve patient outcomes in a variety of clinical scenarios by providing clinicians with more personalized and effective treatment options. This includes the following:

- Cancers progressing on standard-of-care treatment: OncoIndx can help identify the specific genetic alterations driving cancer, and suggest alternate treatment options tailored to the individual patient's genetic profile.
- Cancers where tailor-made treatment will enhance survival: OncoIndx can help identify biomarkers and mutations that drive a patient's specific cancer, which can inform the development of personalized treatment plans.
- Cancers showing resistance to conventional treatment: OncoIndx can help identify the genetic alterations responsible for treatment resistance, allowing clinicians to select alternative treatment options that may be more effective.
- Cancers where a combination of targeted drugs and/or immunotherapy could benefit: OncoIndx can identify potential combination therapy options based on a patient's genetic profile, potentially leading to better treatment outcomes.

Genomic markers and a signature covered in OncoIndx:

A. OncoIndx identifies the following alterations and suggests treatment options based on the results.

- 50 Translocations (fusions)
- Genome-wide CNV backbone
- Genome-wide LOH markers
- 47 HRR (Homologous Recombinant Repair) genes
- Genome-wide HRD scoring (based on an aggregate of LOH, LST, TAI and HRR)
- Covers relevant 339 Intronic and 15719 exonic regions
- MSI (including microsatellite hotspots and MMR genes)
- 36 Pharmacogenomic markers
- TMB (Tumor Mutational Burden)

B. Types of cancer therapies covered

OncoIndx aids oncologists with treatment decisions related to primary forms of cancer treatment like:

- Targeted Therapy
- Immunotherapy
- Selected Chemotherapies

Advantages of OncoIndx

The identification of genome variants using a targeted gene panel with increased precision and coverage depth involves the comparison of sequencing data obtained from an experimental sample and a control sample with a reference genome. During a sequencing reaction, a given base pair is amplified and read several hundred times (1000x for tissues and 5000x for blood).

OUR SOLUTIONS (contd..._

The Fragmentation of DNA fragments during the library preparation step is done based on the quality and quantity of the nucleic acids obtained from the sample. To determine cancer-causing aberrations based on the number of deviations between sequence reads, it is crucial to have a high number of total reads (deeper coverage) for a confident diagnosis. The deeper coverage of the DNA fragments is important as sub-optimal depth sequencing could miss the unique parts of the DNA sequences between two samples if it reliably fails to read the unique fragments of the DNA sequences. There are four main reasons for this requirement:

- Deeper coverage for the rare mutations: Many cancer-causing mutations are rare, and a high depth is required to capture them.
- Low Tumor Purity: The tumor sample is usually pervaded with other cells that make up the tumor microenvironment (TME) along healthy tissue. In many cases, cancerous cells could make up only a minor fraction of the total sample, reducing the overall tumor purity. A cancer-causing mutation's accompanying decline in abundance could preclude its successful capture in genomic tests with a sub-optimal coverage.
- Presence of sub-clones: Intra-tumoral heterogeneity can lead to the development of multiple subclones within a single sample, each with unique mutational characteristics. These conditions can change the diversity and abundance of the relevant mutation and can dilute genomic alterations of interest.
- Chromosomal gains and losses: A physical genomic alteration can cause gross changes in the number of bases at a particular location, leading to a modified mutation abundance in the genome.

The utilization of whole-exome panels typically pertains to exploration studies; however, the OncoIndx system employs a specialized and focused gene panel consisting of over 1000 genes that are relevant to cancer therapy. This solution offers increased sensitivity, specificity, and reproducibility, resulting in enhanced precision and improved identification of rare cancer-associated variants. Moreover, OncoIndx is an all-encompassing genomic testing panel, providing oncologists with actionable information via a single assay.

"OncoIndx can reduce treatment abandonment by recommending alternative therapeutic targets for hard-to-treat cases"

One of the biggest fears for cancer patients is the possibility of running out of treatment options. Unfortunately, one of the leading causes of cancer patients succumbing to the disease is treatment abandonment due to the lack of an actionable target. Therefore, it is imperative to identify alternative treatment strategies that can help patients continue their fight against cancer.

"OncoIndx test can help reduce instances of treatment abandonment by providing critical insights into alternative therapeutic options"

The targeted gene panel screens for cancer-related genes that cause acquired therapeutic resistance. This screening can identify compensatory mechanisms and alternative therapeutic options. Hence, it can provide oncologists with valuable insights and actionable information to help cancer patients continue their fight against the disease.

"OncoIndx's targeted gene panel is well-suited for the detection of ctDNA in liquid biopsies"

The minimal invasiveness of liquid biopsy has garnered considerable attention lately. A liquid biopsy entails screening circulating (ct) DNA released by cancerous tissue in the bloodstream, thereby providing a spatiotemporal evaluation of the disease. Liquid biopsies are less invasive and more easily accessible and less painful than traditional biopsy methods, making them a promising option for diagnosing and monitoring cancer.

Liquid biopsies can be alternative for:

- Predicting the risk for recurrence,
- Assessing divergence in metastatic sites and primary sites
- Evaluating a treatment response over time.

However, the effectiveness of liquid biopsy is contingent on the assay's sensitivity and specificity in capturing trace amounts of ctDNA in the body.

"OncoIndx with its in-depth coverage (5000x) is well-suited for analyzing liquid biopsy samples, as it can provide highly sensitive and specific detection of cancer biomarkers form ctDNA in the blood"

This is particularly useful in cases where traditional biopsy methods are not feasible or do not provide sufficient tissue samples for analysis. OncoIndx which can process liquid biopsy samples holds significant value as an alternative diagnostic tool for cancer.

"OncoIndx is a useful tool for screening pharmacogenomic determinants of toxicity and adverse events in cancer patients"

The dosage of chemotherapy is a key factor in its effectiveness. Hence, determining the optimal dose, frequency, and other parameters of chemotherapy is crucial to achieving a successful outcome. The low dosage can lead to failure, allowing cancer to thrive, while the high dosage often causes adverse effects and toxicity leading to other health problems.

Analyzing a patient's genomic profile through OncoIndx can provide important insights into chemotherapy's potential risks and benefits. The presence of 36 pharmacogenomics-relevant markers in the test could be utilized to pre-screen patients and identify those who may be more susceptible to the toxic effects of chemotherapeutic agents.

By understanding how a patient's genetic makeup may affect their response to treatment, doctors can make more informed decisions about the optimal dosage and regimen to use, potentially improving the effectiveness of the treatment while minimizing the risk of adverse effects.

"OncoIndx Reporting - Harnessing the Power of AI and ML for Precision Oncology"

OncoIndx test comes with a cutting-edge reporting solution that combines the power of artificial intelligence (AI) and machine learning (ML) along with the expertise of oncologists. By providing clear, actionable genomic findings and a secure, data-driven platform for collaboration and decision-making, OncoIndx reporting is leading the way in personalized medicine.

The OncoIndx report is a powerful tool for oncologists, providing clear, unambiguous, and actionable genomic findings that are essential for developing patient-specific treatment plans. The report provides a detailed description of patient-specific genetic mutations and pathways in accordance with international guidelines and is based on highly reliable and internally curated knowledge databases (iKb). At the heart of the OncoIndx report is iCARE, the virtual genomic lab of oncologists.

"AI-powered precision monitoring iCare console is a virtual genomic lab designed by the oncologists for the oncologists"

iCare allows doctors to visualize genomic variants in real-time, access high-level interactive genomic reporting, and leverage a rich database of reference literature. With iCARE, oncologists can conduct a world-class molecular tumor board, enabling collaboration and data-driven decision-making.

The iCare console is end-to-end encrypted and complies with regulatory requirements, ensuring patient privacy and data protection. By leveraging the power of AI and ML, OncoIndx reporting and iCARE provide oncologists with the tools they need to deliver the best possible care to their patients.

NOTES

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