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The Advent of Multi-Omics Cancer-Diagnosis: NGS, Bioinformatics and Precision Oncology using Tata Memorial Centre and Homi Bhabha Cancer Model

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ABSTRACT

Recent years have led to the exploration of cancer diagnostic techniques. No longer are we stuck on the one-size-fits-all approach, but a method of diagnosing cancer specific to each individual, using a combination of numerous oncological tests at once. This review explains why the Homi Bhabha Cancer Hospital and Research Center in New Chandigarh has established a centralized system via the hub and spoke model, allowing different communities in India to have decentralized access. Multi-Omics Oncology diagnostics have brought our labs from generalized cytotoxic treatment to specific analysis of molecular aberrations using techniques such as polymerase chain reaction (PCR), next-generation sequencing (NGS), and fluorescence in situ hybridization (FISH). We will also learn about the additional step of our multi-factor detection becoming intelligent clinical diagnostics with the help of GATK and statistical modeling (Kaplan-Meier survival analysis)

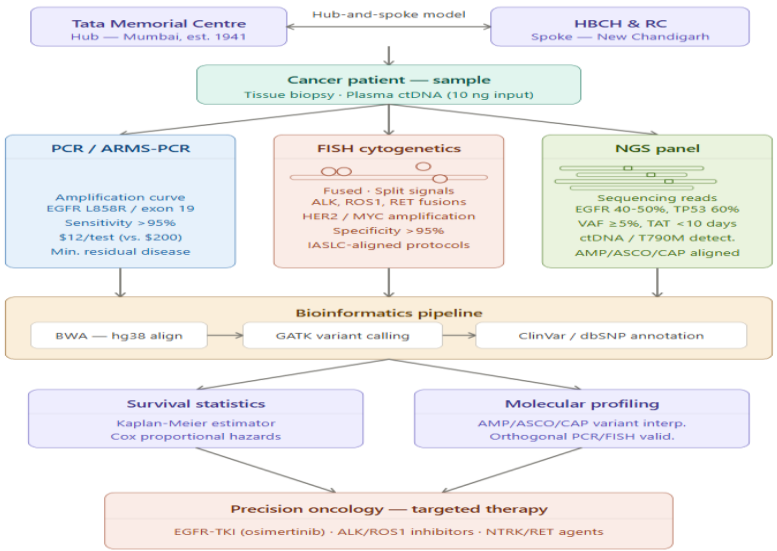
Introduction

The Strategic Vision of TMC and HBCH&RC

The Tata Memorial Center (TMC) has been a pioneer in oncology research in India. Since its inception in 1941, it has significantly centered around the paradigm shift of cancer determination from a one-size-fits-all approach to the new evident precision-based medicine with multi-disciplinary platoon operations throughout cancer-specific groups. Additionally, TMC has been expanding to other cities, such as the Homi Bhabha Cancer Hospital (HBCH&RC) in New Chandigarh, to have cutting-edge research reach to larger scale population. This shift will emphasize a range of possibilities of interdisciplinary work that applies molecular biological studies to clinical oncology, where the underlying genetic processes are used to address complex human health issues.

The growing TMC network into tertiary hubs, such as the Homi Bhabha Cancer Hospital and Research Center (HBCH&RC), will ensure the decentralization of the hub-and-spoke model, which is crucial to obtaining world-class oncology services in a resource-limited setting and promoting standardized diagnostic procedures and locally developed innovations (Tata Memorial Centre of Oncology., 2024)

Advanced Molecular Modalities in Diagnostic Oncology



PCR-based assays and indigenous innovation

Polymerase chain reaction (PCR) is the foundation of molecular diagnostics in cancer biolog and is well-known for its remarkable sensitivity in analyzing small residual disease and hotspot mutations with allele frequencies as low as 1%. (Mauger, How-kit, and Tost,2017). It`s use is expanded by variants like real-time quantitative PCR (qPCR), reverse transcription PCR, and digital PCR (dPCR) that offer rapid, cost-effective, and highly specific detection of genetic aberrations, vital for prognosis and further choice of therapies (Zhang, and, Tian, 2024)

Amplification Refractory Mutation System-PCR (ARMS-PCR) has established itself as a fi-lineine test in the field of Indian oncology practice and detection of epidermal growth factor receptor (EGFR) exon 19 deletions and L858R mutations of the gene particularly present in NSCLC, which comprises more than 80% of lung cancer cases in the country (Lieu *et al*., 2011). The sensitivity and specificity of this allele-specific PCR method are greater than those of Sanger sequencing, and it directly guides the application of EGFR TK inhibitors (Jia *et al*., 2017). A transformative indigenous innovation by researchers at the Tata Memorial center and ACTREC has revolutionized the accessibility of EGFR in non-small cell lung cancer (NSCLC) mutation testing using the Amplification Refractory Mutation System (ARMS-PCR): developing low-cost ARMS kits that reduce expenses from ~$200 to a mere $12 per test (Lieu *et al*., 2011). This 16-fold price drop has radically broadened testing volumes, breaking the budget of underserved populations, flattening the rate of mutation detection of 20% to >60% of eligible NSCLC cases, and fair precision oncology.

Fluorescence in situ hybridization (FISH)

Fluorescence in situ hybridization is the gold standard cytogenetic assay used to identify structural chromosomal alterations, such as fusions (e.g., ALK, ROS1, and RET), amplifications (e.g., HER2, MYC), and deletions, in solid tumors, such as non-small cell lung cancer (Hofman *et al*., 2023). It is a technique where DNA probes bearing a fluorescent label are hybridized with complementary sequences on metaphase chromosomes or interphase nuclei, and different genetic aberrations can thus be directly visualized by fluorescence microscopy. The increased specificity of dual-color break-apart probes (>95% detection of translocations) is achieved by labeling the 5' and 3' regions of the target genes with different fluorochromes (e.g., orange and green), resulting in prompting the fusion of signal in the wild type genes but breaking patterns on the rearranged loci (Joseph, 2017). The standardized protocols in the context of HBCH&RC use a minimal mark of ≥15% tumor cells with break-apart signals (usually 50-100 nuclei scored) to be considered positive, in addition to great inter-observer reliability and consistency amidst other international standards such as those of IASLC (Frontiers | Performance.,2017).

Next-Generation Sequencing (NGS)

High-throughput profiling next-generation Sequencing has completely transformed the diagnostic profile of the oncology setting by allowing, in parallel and high-throughput mode, an interrogation of hundreds to thousands of cancer-relevant genes with respect to mutations, insertions/deletions, copy number changes, and structural rearrangements (Srivastava *et al*., 2016). This is much more powerful than single-gene assays, which reveal rare or comorbid actionable mutations, informing the choice of a personalized therapy, such as detection of concurrent EGFR and TP53 mutations that dominate Indian non-small cell lung cancer groups (Vermorken *et al*., 2023). The prevalence of actionable alterations in EGFR (34.1%), TP53(37%), and KRAS(13.3%), respectively, in large-scale studies including comprehensive genomic profiling (Jiang *et al*., 2024). Instruments such as the Illumina Pillar oncoReveal Solid Tumor v2 which is a dedicated NGS panel have been quite useful in a resource-limited environment such as the Homi Bhabha Cancer Hospital and Research Centre, providing excellent sensitivity to low-frequency variants down to 5% variant allele frequency with turnaround times as short as 10 days.

In addition, the introduction of liquid biopsies has greatly increased the access to NGS especially in the surveillance of minimal residual disease or learned resistance in more advanced situations (Yamin *et al*., 2023). NGS-based on circulating tumor DNA (ctDNA) only needs 10 ng of circulating tumor nucleic acid (ctDNA) input, so that serial sampling is feasible and invasive tumor biopsies are not required, with evidence supporting the use of ctDNA profiling as shown by Indian protocols showing EGFR T790M resistance mutations following tumor escape of TKI in up to 60% of cases (Ho *et al*., 2024).

Computational Frameworks and Statistical Analysis

Bioinformatics Pipelines for Variant Interpretation

Bioinformatics processing is a rigorous process required to convert raw genomic data into clinical insights. The standardized workflows include alignment to the hg38 reference genome with the help of BWA and variant discovery with the help of Genome Analysis Toolkit (GATK) (Hayes, *et al*., 2024). The clinical significance of identified variants is determined by feature-based annotation against databases such as ClinVar and dbSNP (Dtatabase resource for t…, 2016). The variant interpretation is given through an open-source model like ClinBioNGS that gives a transparent analysis of the Indian context.

At Tata Memorial Centre and its affiliates such as HBCH&RC, precision oncology is upheld via integration of unified bioinformatics pipelines. Providing that variant interpretation is performed in a manner that complies with AMP/ASCO/CAP standards, where significant results are also validated using PCR or FISH. The results of this multi-modal strategy shows an improved detection rate of infrequent fusions (e.g., RET, NTRK) from less than 5% to more than 15% leading to new therapies (Grunewald *et al*., 2020).

Statistical Modeling of Clinical Outcomes

Validation of research efficacy requires statistical proficiency. Survival analysis is the most important tool in oncology, which can be used to provide survival functions estimates using the Kaplan-Meier Estimator. Moreover, Cox Proportional Hazards Model gives Hazard Ratios (HR) to calculate the effects of several clinical variables at one time (Huang, *et al*., 2025).

Statistical proficiency is essential for validating research efficacy. The Kaplan-Meier Estimator is used to estimate survival functions. Furthermore, the Cox Proportional Hazards Model provides Hazard Ratios (HR) to determine the impact of multiple clinical variables simultaneously (Masuda *et al*., 2024).

Conclusion and Future Directions

This is the forefront of Indian oncology with the combination of molecular applications, bioinformatics and high-level statistics at HBCH&RC. With robotic-assisted surgery and proton therapy being introduced to the institute, the role of precise diagnostics is going to be even more increased. Potential researchers still have the responsibility of closing the divide between molecular biology and bed-side care in order to accomplish the role of ensuring fair delivery of oncology services.

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