A study for Cancer Biomarkers and identify the gaps for Cancer Biomarker in the Biomarker market

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Abstract

Biomarkers or biological markers are molecules that indicate normal or abnormal process in the body. Biomarkers are found in blood, stool, urine other body fluids and in tissues. In cancer, biomarkers may be any substances produced by the cancer tissues. During apoptosis and necrosis of the cancer cells, these biomarkers are released into the blood stream, facilitating and promoting metastatic activity in organs. Identifying these biomarkers could help in detecting the type of cancer and the mode of treatment required.

The research conducted was exploratory. The aim of this research work was to study the local market for cancer biomarker, interact with oncologists and identify the gaps that exist in cancer biomarker market. The sample size was 15 respondent (medical oncologist) from selected cancer hospitals in Bangalore. Convenience sample technique was adopted during data collection process.

The study also discusses about the key players in global as well as Indian market and to identify the gaps existing in the market. It also helped us to analyse the attitude of doctors towards cancer biomarker.

Advancement in technology, increasing expenditure in healthcare sector, speed & accuracy of diagnosis of cancer are the major factors that drive cancer biomarker market. Factors like poorly suited regulatory and reimbursement systems, high capital investment, low benefit cost ratio and technical issues related to sample collection and storage can restrain the market growth to a certain extent. The study revealed an attractive opportunity in the cancer biomarkers marker.

Key words: Cancer biomarkers, Oncologist, Diagnostic tests

INTRODUCTION

In India, estimated number of people living with cancer is around 2.25 million and over 11 lakh new cancer patients are registered every year. Early detection of cancer has high chance of recovery. In cancer, biomarker may be any substances which is produced by the cancer tissues. During apoptosis and necrosis of the cancer cells, these biomarkers are released into the blood stream, facilitating and promoting metastatic activity in organs. Guide treatment decisions, monitor treatment, predict the chance of recovery and recurrence.

Global cancer biomarkers market size is expected to reach $15,737 million by 2022, registering a CAGR of 13.3% growth. Global Cancer biomarker market is broadly segmented based on profiling technology, biomolecules, cancer type, application, and geography.

By profiling technology, the cancer biomarker industry is segmented into omic technologies, imaging technologies, immunoassays, and cytogenetics based tests. Omic technologies segment occupies the largest cancer biomarker market size. Based on biomolecules, the cancer biomarker industry is segmented into genetic biomarkers, protein biomarkers, and glycoprotein biomarkers. Genetic biomarkers occupies the largest cancer biomarker market share. The various cancer type include breast cancer, lung cancer, prostate cancer, colorectal cancer, stomach cancer, and others, among which breast cancer accounts for the largest cancer biomarker market size. Based on application, the market can be segmented into diagnostics, drug discovery and development, prognostics, risk assessment, and others. Prognostics segments occupies the largest cancer biomarker market share. Geographically, the global cancer biomarkers market is analyzed across North America, Europe, Asia-Pacific, and LAMEA. North America is the leading revenue generating region, due to higher rate of occurrence of cancer, awareness regarding cancer, an increased number of cancer biomarker tests, whereas Asia-Pacific is growing fast due to increased disposable incomes, increased awareness, and rising affordability for advanced cancer treatments.

The Asia-Pacific cancer biomarkers market is fragmented, due to an increased number of market players, who are focusing on R&D, market expansions, partnerships, and mergers in order to experience stable growth. The market has been noticing technological developments on a large scale for the past couple of years. The Asia-Pacific cancer biomarkers market is expected to register a CAGR of nearly 12% during the forecast period, 2019-2024. There has been a paradigm shift in healthcare, where early diagnosis or risk assessment in cancer has been possible especially in countries, such as China, India, Japan, etc.

In India there are several good private laboratories that provide high quality and reliable genetic testing, for a cost, ranging from INR 5,000 to INR 40,000 this may not be affordable to many families. Presently it could be observed that no Government hospitals are providing genetic testing for cancer. There is a lacunae in the local market of cancer biomarker.

The main objective of the study is to identify the most commonly treated type of cancer, to identify the tests for diagnosis of Cancer, to study the local market of Cancer Biomarkers, to identify the gap that exist in the Cancer Biomarkers market and to study the attitude of Doctors towards the Cancer Biomarkers.

METHODOLOGY

The study was exploratory and the sample was collected across Cancer hospitals in Bangalore. The technique used for collection of sample was convenience sampling. The sample size was 15 medical oncologists from selected hospitals in Bangalore. Data collection method was questionnaire and MS excel was used to analyse the data collected. Pie charts and Bar graphs were used.

List of hospitals to be visited

A list of 30 hospitals were short listed for the study which are located at various parts of Bangalore. Out of 30 selected hospitals 6 were cancer specialty hospitals, 21 were multi- specialty hospitals and 3 medical colleges.

Data collection

Primary data was collected through questionnaire. A validated simple questionnaire was prepared and used to collect data from the identified sample. The sample size was 15 respondents for medical oncologist of selected cancer hospitals in Bangalore. The basic aim of the survey was to find the cancer biomarker tests offered by the hospitals. Convenience sampling technique was adopted during data collection process.

The secondary data was collected from national and international publications, magazines, articles and journals. The secondary data also includes the websites of laboratories offering cancer biomarker tests.

A focus group discussion chaired by a monitor who would pose open ended questions, the answer of which are not just 'yes' or 'no' but would be discussed in the forum by panel members was designed. The team of 6-9 members would be the panel and any diversions from the topic of discussion the moderator will route the discussion back to the topic. A focus group discussion (FGD), was conducted with a panel of 7 Oncologists, who had great experience in their field.

The main aim of the discussion was to identify the awareness amongst doctors about cancer biomarker tests and whether they prescribed diagnostic tests based on cancer biomarkers. The group also discussed about the cancer statistics India and in global scenario.

Questionnaire design

The questionnaire was simple, easy and straight forward. The language was easy and understandable. The aim of the questionnaire was to meet the objectives of the study.

The questionnaire were formed to study the cancer biomarker market and to find the attitude of doctors towards cancer biomarker tests. It also help to find the cancer statistic of Bangalore. The questionnaire covered the most common type of cancer, their diagnosis tests, price and the laboratories offering the test.

Questionnaire for Hospitals/Doctors

Form #-
Name of the hospital-
Area –
No. of beds in Hospital (Oncology)-
Name –
Mobile no.-
E-mail id-
Once the survey has been completed, the summary of the project and its findings will be emailed to you.
Thank you in advance for the support in participating in this survey.

1. Most commonly treated type of Cancers in your Hospital?
   a. Lung Cancer   c. Oral Cancer   e. Colorectal Cancer
   b. Breast Cancer   d. Cervical / Prostate Cancer   f. Others Cancers

2. Top tests you prescribe for diagnosis of Cancer
   a. ....   b. ....   c. ....

3. Price range for these tests
   a. 5,000- 10,000   b. 11,000- 30,000   c. 31,000- 50,000   d. 51,000 & above

4. Labs offering diagnostic tests
   a. ....   b. ....   c. ....

5. Are the samples sent to labs outside India, if yes, which country?
   a. ....   b. ....   c. ....

6. Does the price vary from lab to labs?
   a. Yes   b. No

7. What is the range of price variation/test?
   a. 1000-2000/test   b. 2000-5000/test   c. >5000/ test

8. In a month how many patients are diagnosed with cancer?
   a. 1- 5   b. 6-10   c. 11- 20   d. More than 20

9. Approximately how many tests you prescribe in a month?
   a. 1- 5   b. 6- 15   c. 16- 30   d. 31 & Above

10. What is the approximate time duration to get the results?
    a. 1- 2 weeks   b. 2-4 weeks   c. 4-5 weeks   d. 5 & above

11. Are you satisfied with the results given by the labs?
    a. Yes   b. No

12. Does late diagnosis affect the treatment?
    a. Yes   b. No

13. Have you heard of Cancer Biomarkers?
    a. Yes   b. No

14. Have you prescribed tests based on Cancer Biomarkers? If yes, which one?
    a. ....   b. ....   c. ....

15. Will you consider prescribing Cancer Biomarker diagnostic tests?
    a. Yes   b. No

16. If yes, why?

17. If no, why?

RESULTS AND DISCUSSION

The study was conducted as per the proposed design which was an exploratory study where samples were collected from various Cancer hospitals in Bangalore. Convenience sampling was carried out and 15 medical oncologists responded to the questions posed. Data collection method was questionnaire as already stated. MS-Excel was used for data analysis.

Outcome of focus group discussion

Each individual participants had their suggestions on creating awareness about cancer biomarker tests. All oncologists in the panel had a thorough knowledge about the cancer biomarkers. They were more satisfied with the results given by the cancer biomarker tests than the other traditional way of diagnosis (Biopsy, CT scan, PET scan, etc.). They believed that the only reason for not prescribing the biomarker test was due to the high price of the tests. These tests are prescribed to patients who can financially afford the cost of the test. In traditional way of diagnosis, the doctor prescribes multiple tests to analyze the type of cancer. It was observed that all the multiple tests prescribed did not exceed the price of single genomic biomarker test. Doctors were ready to prescribe the tests if it were cost effective and affordable to all.

Questionnaire discussion

All the oncologists believed that the most commonly treated type of cancer was breast cancer followed by lung cancer (40%), cervical/prostate cancer (40%), oral cancer (33.3%) and colorectal cancer (33.3%). This corresponds to the study on cancer in India published by National Institute of Cancer Prevention Research (NICPR) where it is stated that lung cancer, breast cancer, oral cancer, cervical cancer, prostate cancer and colorectal cancer were the most common types (Figure 1). The most preferred diagnostic test for cancer was biopsy (93.3%) followed by CT scan , PET scan, biomarkers, clinical examination, MRI and mammogram. Biopsy which is the collection of tissue sample from the suggested area of body to diagnose cancer is the most popular mainly due to conventional practice followed by the physicians. CT scan and MRI scan confirms the stage of cancer in the patient. Tumor marker tests are least popular mainly because of the affordability (Figure 2). 66.7% oncologists responded that the price for these diagnostic tests range from INR 11,000-30,000 and rest 33.3% responded to price range from INR 5,000- 10,000. Majority of the doctors felt that the conventional mode of treatment which included blood test, biopsy, CT scan, MRI etc together was priced in the range of INR 11,000- 30,000 (Figure3). 66.7% oncologists suggested the names of various local labs performing the diagnosis tests. Newmedd diagnostics (40%), Onquest Laboratories Ltd (20%), Strand Life Sciences Private Limited (20%) and Triesta (20%) were the most recommended oncological diagnostic laboratories. Other laboratories offering cancer diagnostic tests are central lab, Liliac, Medclu, Core, Sampige Onco, Thyrocare, Metropolis, Medgenome and SRL. Newmedd diagnostics, Bangalore is first of its kind, comprehensive nuclear medicine, PET/CT and radionuclide therapy (Figure 4). Majority of the hospitals did not send their sample to laboratories outside India. 20% oncologists from three different hospitals sent their sample outside India to perform tests like Mammoprint, Endopredict and Oncotype Dx. An affirmative response was obtained from 87% oncologists on the price variation of tests in various laboratories. 61.5% oncologists found the price to be in the range of INR 1,000- 2,000, followed by 30.8% responding to price range INR 2,000- 5,000 and 7.7% oncologist responded to INR 5,000 & above. This price variation could be reduced by competitive pricing (Figure 5). 46.7% oncologists found more than 20 patients are diagnosed with cancer whereas 33.3% oncologists have seen around 11-20 cases in a month and 20% oncologists have around 6-10 patients diagnosed with cancer in a month. The general trend observed was an increase in the number of patients falling prey to cancer (Figure 6). 66.7% oncologists prescribed more than 30 tests, followed by 20% oncologists who prescribed 16-30 tests and the remaining 13.3% oncologists prescribed 6-15 tests in a month. Generally multiple tests are performed to diagnose cancer, but in few cases one or two tests can confirm the same (Figure7). 93.3% oncologists gave an affirmative reply was that results for diagnostic tests would generally be available within 1-2 weeks. 93.3% oncologists were satisfied with the results given by the diagnostic laboratory. 86.7% oncologists responded that late diagnosis affect the treatment of cancer and 13.3% oncologists responded it would not affect the treatment. Majority of the doctors felt the delay could affect patient as the cancer may progress or spread to other part of body. In that case treatment decision would be difficult for the oncologists (Figure 8). The study revealed all 100% of oncologists were aware of the cancer biomarker and their advantages. Most of them said they wished to prescribe them and some even prescribed them regularly depending on the patient's affordability. All oncologists included in the study prescribed diagnostic tests based on cancer biomarkers. 66.7% oncologists prescribed CEA cancer biomarker test followed CA19.9, AFP, CA 125, beta HCG, ER & PR, HER2 & EGFR cancer biomarker tests and other responses include BRCA, Thyroglobulin, PDL, KRAS, NRAS, MIS, CD markers, immunotherapy and foundation one (Figure 9). 93.3% oncologists prefer prescribing cancer biomarker diagnostic tests. This affirmative reply reflects the rising popularity of biomarkers.

Most commonly treated type of Cancers in your Hospital
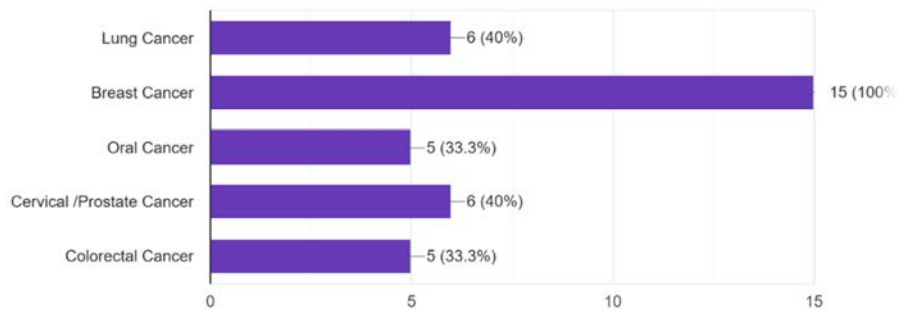15 responses

Figure 1: Most commonly treated type of cancer

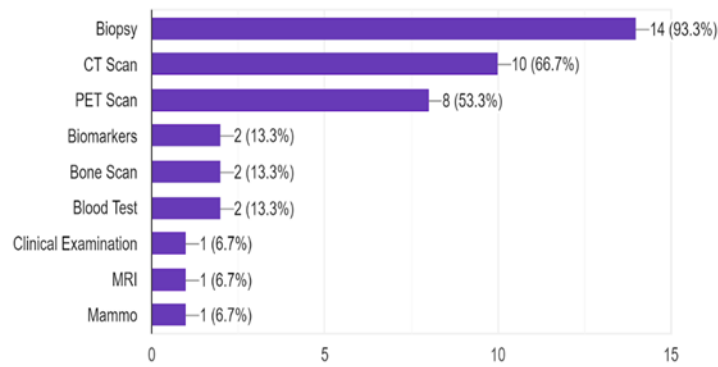## Top tests you prescribe for Diagnosis of Cancer
15 responses

Figure 2: Tests prescribed for diagnosis of cancer
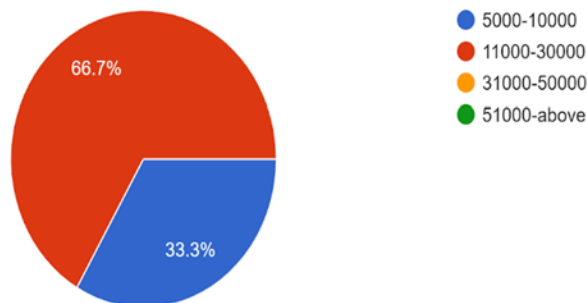
Price Range for these tests
15 responses

Figure 3: Price range for the tests
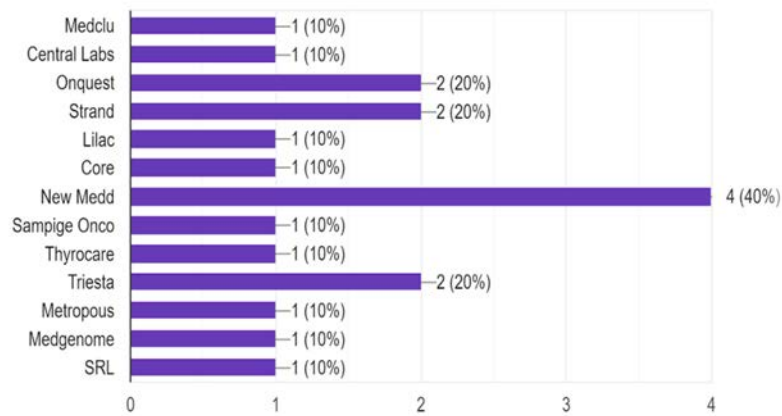
Lab offering diagnostic tests
10 responses

Figure 4: Labs offering diagnosis tests

What is the range of price variation per test
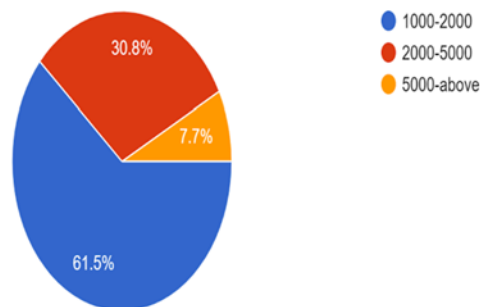13 responses

Figure 5: Price variation from labs to labs

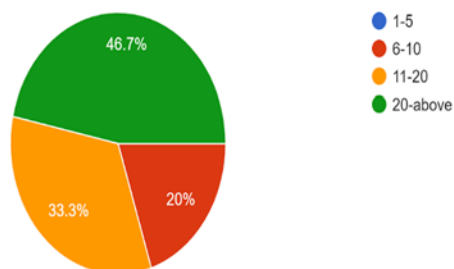## In a month how many patients are diagnosed with cancer
15 responses

Figure 6: Patients diagnosed with cancer in a month

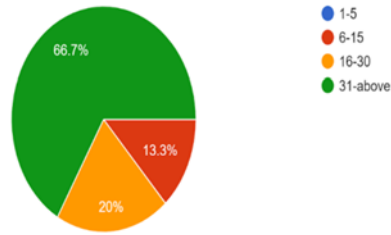Approximately how many tests you prescribe in a month

15 responses

- 1-5
- 6-15
- 16-30
- 31-above

Figure 7: Number of tests prescribed in a month

Does late diagnosis affect the treatment

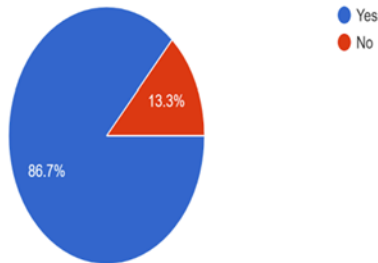15 responses

- Yes
- No

Figure 8: Late diagnosis affect the treatment

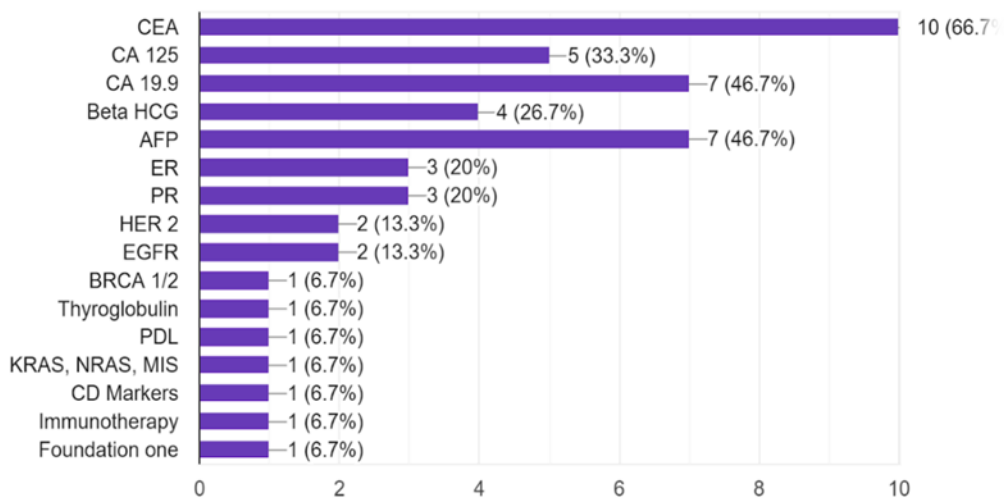Have you prescribed tests based on cancer biomarkers, If yes Which one?

15 responses

Figure 9: Prescribed tests based on Cancer Biomarkers

Table 1.0 Commercially Available Advanced Cancer Biomarker Tests

SL NO.	Name of test	Company offering	Sample required	Sequencer	Genes covered and mutation type (if specified*)	Additional analysis	Price	Turn around time	Year launched
1	FoundationOne	Foundation medicine	FFPE*	Illumina	315 genes (+ 28 introns)	MSI*** TMB****	5000 USD	14 days	2011
2	Caris Molecular intelligence	Caris Life Science	FFPE*	Illumina	>600 genes	IHC***** MSI*** TMB**** ISH******	6500 USD	10-14 days	2014
3	Paradigm Cancer Diagnostic-PCDx	Paradigm	FFPE*	Ion Torrent	186 genes	IHC***** MSI***	4800 USD	5 days	2014
4	OncoDEEP	OncoDNA	FFPE*	Ion Torrent	75 genes	IHC***** MSI*** TMB****	3500 USD	7 days	2014
5	OncoSTRAT & GO	OncoDNA	FFPE* & 2- 10 ml blood samles (for ct DNA)	Ion Torrent	>500 genes	IHC***** MSI*** TMB****	5800 USD	10 days	2016
6	Tempus Xt/Xo	Tempus Labs	FFPE* and blood or saliva sample for normal DNA	Illumina	595 genes (xT) 1711 genes (xO)	MSI*** TMB****	4800 USD	14- 21 days	2017
7	Onco Vantage Solid Tumor Mutation Analysis	Quest Diagnostics	FFPE*	Ion Torrent	34 genes	_	1800-3000 USD	14 days	2014
8	Oncomine Dx Target Test	Thermo Fisher Scientific	FFPE*	Ion Torrent	23 genes (NSCLC**)	_	_	4 days	2017

*FFPE-Formalin-fixed Paraffin-embedded, **NSCLC-Non-Small Cell Lung Cancer, ***MSI- Microsatellite Instability, ****TMB-Tumor Mutation Burden, *****IHC- Immunohistochemistry, ******ISH- In situ hybridization

CONCLUSION

According to the study conducted it was evident that majority of the respondents were aware about the biomarkers and their application in cancer. Prescription rate was low because of the high price of the cancer biomarker tests, which is not affordable to the majority of the population in India. There is an attractive opportunity in cancer biomarker market where the global biomarker market is projected to reach 20.48 million USD by 2022. Factors that drive the cancer biomarker market advancement in the technology, increasing expenditure in the healthcare sector and speed & accuracy of the diagnosis of cancer. Factors like poorly suited regulatory and reimbursement systems, high capital investment and low benefit-cost ratio and technical issues related to sample collection, storage and shipping can restrain the market growth to a certain extent. Personalized medicine and companion diagnostic field can bring up good opportunity to the cancer biomarker market.

Acknowledgements

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