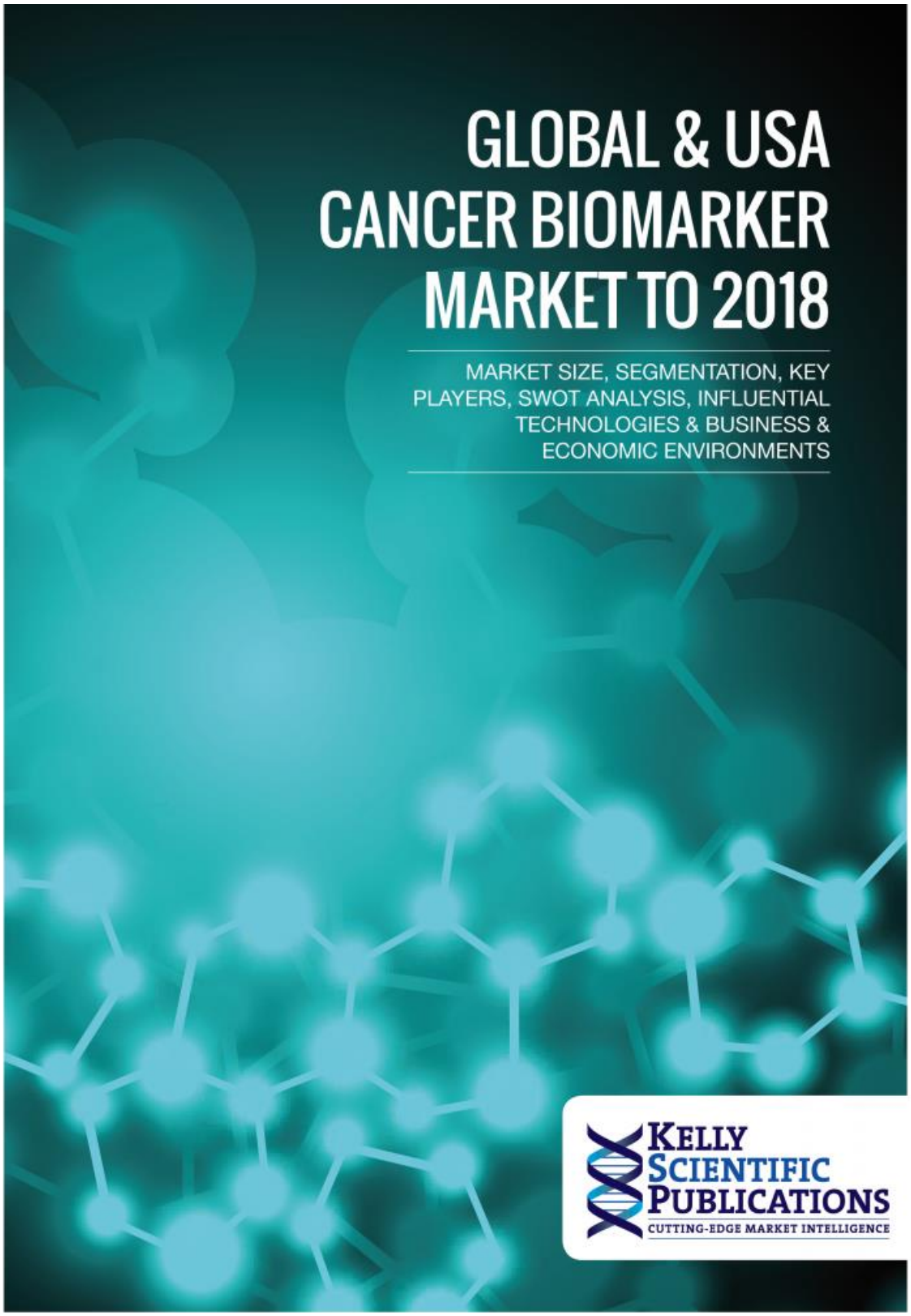

GLOBAL & USA CANCER BIOMARKER MARKET to 2018 (Identification, Technologies, Market Analysis, Competitor Profiles, Companion Diagnostic Co-Development, Business Strategies, Industry Trends, and Pipeline Analysis)

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1.0 Executive Summary

"GLOBAL & USA CANCER BIOMARKER MARKET to 2018 (Identification, Technologies, Market Analysis, Competitor Profiles, Companion Diagnostic Co-development, Business Strategies, Industry Trends, and Pipeline Analysis)" by Kelly Scientific Publications is a comprehensive report on the cancer biomarker industry and its impact on the health system. This report tackles the growing market interest in oncogenic biomarkers, personalized medicine, companion diagnostics and the associated market environment.

Cancer biomarkers are molecular or genetic moieties (e.g., cells, proteins/peptides, genetic mutations, gene products, enzymes, or hormones) that not only are readily identifiable, but easily quantified in the lab setting. They function primarily to identify or correlate significantly with the severity or occurrence of a certain disease state. The rise in number of oncogenic biomarkers over the last number of years has massive potential in the healthcare industry and serves to propel both the personalized medicine and companion diagnostic markets.

One of the most import aspects of biomarkers is their use to diagnose and assess the progress of disease states in patients. As quantitative markers, these agents also offer the ability to monitor response to certain drug treatments and so are important in the area of personalized medicine.

Individualized, targeted or personalized medicine aims to increase the efficacy of therapeutics via genetic testing and companion diagnostics. Personalized therapeutics and associated companion diagnostics will be more specific and effective thereby giving pharma/biotech companies a significant advantage to recuperate R&D costs. Personalized medicine will reduce the frequency of adverse drug reactions and therefore have a dramatic impact on health economics. Developmental and diagnostic companies will benefit from lower discovery and commercialization costs and more specific market subtypes.

This report describes the current technologies that are propelling the cancer biomarker and companion diagnostic market. It examines the current genetic diagnostic tests and companion diagnostic assays that are in use by the medical and pharmaceutical industry today. Current developments in personalized medicine and the pharmacogenomics revolution are discussed. The emerging trends that appear in the global market and the most developed market (US) are elucidated and analysed. This study reveals market figures of the overall biomarker market and the cancer biomarker space (2013-2018). Forecast projections and future growth rates are provided to give the reader a forthcoming perspective of this growing industry.

The study also provides a comprehensive financial, business strategy and product review of key players in the cancer biomarker industry. Strategic drivers and restraints of this market are revealed and market opportunities and challenges are identified.

In summary, the cancer biomarker and associated companion diagnostic market have huge opportunities for growth. This industry will revolutionize the healthcare system and will improve therapeutic effectiveness and reduce the severity of adverse effects. It has enormous potential for investment and the emergence of genetic-based in vitro diagnostics.

1.1 Objectives of Report

This is a comprehensive account of the market size, segmentation, key players, SWOT analysis, influential technologies, and business and economic environments. The report is supported by **280 tables & figures over 232 pages**. This report is presented as follows:

- By **Company** (e.g., 23andMe, AFFYMETRIX, ATOSSA GENETICS, NODALITY, deCode /Amgen, CELERA, MYRIAD, FOUNDATION MEDICINE, GENOMIC HEALTH)
- By **Geography** (Global, US)
- By **Sub-market** (Global Biomarker Market, Cancer Biomarker Market, Global Cancer Profiling Technology Market)

A wealth of **financial data & business strategy information** is provided including:

- Up-to-date company financials, sales & revenue figures
- Revenue and market forecasts up to 2018
- Business model strategies for diagnostic, pharmaceutical and biotechnology companies
- Therapeutics and Companion Diagnostics (e.g., BRAC Analysis, Oncotype Dx , KRAS Mutations)
- Comprehensive account of company product financials, portfolios & kits

SWOT, **Economic & Regulatory Environment** specifics include:

- Key strengths, weaknesses and threats influencing leading player position within the market
- Technologies driving the market (e.g., New-Generation Sequencing Technologies, Ultra-High Throughput Sequencing)
- Top fastest growing market segments and emerging opportunities
- Top pharmaceutical companies within the cancer biomarker market
- Comprehensive product portfolios, R&D activity and pipeline therapeutics
- M&A activity and future strategies of top companies
- Approved biomarker companion diagnostic tests

- High demand and Unmet Need Enhances the Global Biomarker Market
- FDA Support Increases Biomarker Development
- More Streamlined Clinical Trials
- Significant Growth of High-Impact Oncogenic Biomarker Research
- Advancements in Discovery Technologies
- Challenges of the Oncogenic Biomarker Market
- Variability of Biomarkers within Different Cancer Subtypes
- Integration of Genomics and Biomarker Diagnostics into the Healthcare System
- Ethical Considerations

This report highlights a number of significant pharmacos and gives details of their operations, products, financials and business strategy.

- 23andMe
- Affymetrix
- Ambry Genetics
- Astex Pharmaceuticals
- Atossa Genetics
- BioMerieux
- CuraGen
- Celera Corporation (Quest Diagnostics)
- Celldex Therapeutics
- deCode Genetics (Amgen)
- Foundation Medicine
- Illumina
- Genelex

- Genomic Health
- Myriad
- Nodality
  OriGene Technologies
- Randox
- Qiagen

1.2 Data Sources and Methodology

The project leader and author of this research obtained a Ph.D. in Medicine from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. She has extensive experience in genetics, bionmarker and pharmacogenomic research and development and has conducted post-doctoral studies and lecturing in Trinity College Dublin. With many years of medical writing and publishing the author also has extensive experience and knowledge of molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology.

Sources of information for this report were collected and compiled from company specific corporate websites, annual reports, press-releases, international scientific and medical journals and news and research reports. Graphical and numerical data have been referenced and sourced accordingly. Specific websites were consulted and referenced throughout the completion of this report including that of the Food and Drug Association (www.fda.gov), the National Cancer Institute and other government agencies worldwide. Kelly Scientific Publications has used the most recent statistical and numerical data available. The most reliable of data sources were used in the production of this report, however we cannot guarantee complete accuracy or completeness from secondary information sources.

1.3 Key Findings and Observations

1.3.1 What Makes Cancer Biomarkers so Important for the Healthcare Industry?

Cancer biomarkers are molecular or genetic moieties (e.g., cells, proteins/peptides, genetic mutations, gene products, enzymes, or hormones) that not only are readily identifiable, but easily quantified in the lab setting. They function primarily to identify or correlate significantly with the severity or occurrence of a certain disease state. The rise in number of oncogenic biomarkers over the last number of years has massive potential in the healthcare industry and serves to propel both the personalized medicine and companion diagnostic markets.

One of the most import aspects of biomarkers is their use to diagnose and assess the progress of disease states in patients. As quantitative markers, these agents also offer the ability to monitor response to certain drug treatments and so are important in the area of personalized medicine.

Biomarkers offer significant potential in advancing modern medicine with regards to improving patient diagnosis and treatment options. As many biomarkers are of genetic origin, they can also be used as predisposition markers. Other advantages of these molecular tools include the stratification of patient populations and an increased drug specificity to maximize efficacy and minimize toxicity. Therapies will become more specific as a result of using biomarkers as diagnostic tools, and this will in turn ensure that patients are more responsive to treatment without experiencing un-necessary adverse effects

1.3.2 What Technologies are Used to Identify Novel Biomarkers?

The main technologies that are used to discover biomarkers include bioinformatics, genomics, next generation sequencing, proteomics, nanobiology, systems biology and also the use of stem cells. This report gives a comprehensive analysis of the most important techniques used in industry and R&D today, and reveals which technologies hold the most promise within the market. The report also delves into the complicated practice of biomarker validation and assesses the different phases of validation – from identification to quality control monitoring.

Table 1: Main Technologies Used in the Discovery of Biomarkers

Genomics
Next Generation Sequencing
Bioinformatics
Proteomics
Metabolomics
Nanobiology
Systems Biology
Imaging Technologies
Stem Cells

1.3.3 Increase in Cancer Prevalence is Propelling the Oncogenic Biomarker Market

Over 32 million people globally are living with cancer in 2014. According to Cancer Research UK, over 14.1 million new cancer cases were diagnosed in 2012. Of these, 7.4 million men and 6.6 million women were diagnosed. The most common cancers reported are:

- Lung
- Breast
- Colorectal (bowel)
- Prostate

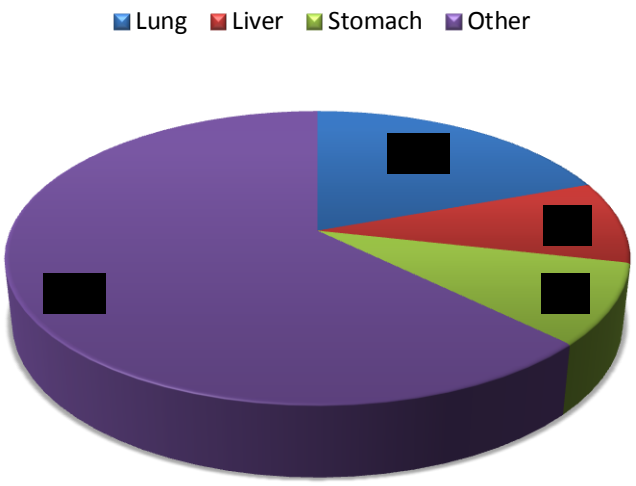
These four cancer subtypes account for 40% of total. In 2012 alone, 8.2 million people died from cancer globally, with 60% of these occurring in less developed regions. Lung, liver, stomach and bowel cancers were responsible for the majority of these deaths, with lung cancer the most significant killer at 20% or 1.59 million deaths. Liver cancer killed 0.8 million in 2012, with stomach cancer killing 0.7 million.

Cancer is the second most common cause of death in the US today, killing one in every four. The National Cancer Institute estimates that 13.7 million Americans have had cancer in the past or are currently suffering from this disease. Recent statistics from the American Cancer Society (ACS) estimated over 580,000 US citizens died from cancer in 2013. Of these, 174,100 deaths could have been prevented. The World Cancer Research Fund estimated that up to 33% of US cancers in 2013 were attributed to lifestyle factors.

Table 2: Top Five Most Frequent Cancers in Men and Women, Globally

Men	Women	Total
Lung	Breast	Lung
Prostate	Colorectum	Breast
Colorectum	Cervix uteri	Colorectum
Stomach	Lung	Stomach
Liver	Stomach	Prostate

Figure 1: Percentage of Lung, Breast and Colorectal Cancer Diagnoses Globally



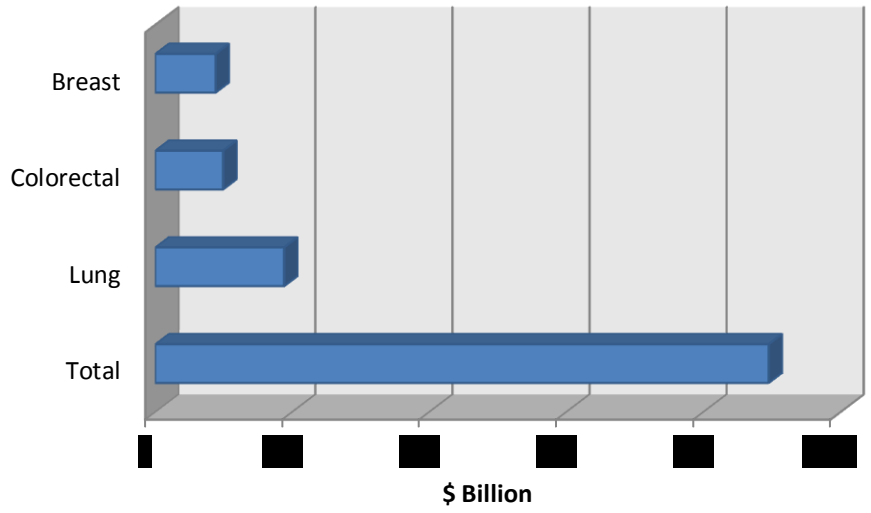
1.3.4 Global and US Economic Impact of Cancer

GLOBOCAN estimates that by 2025, 19.3 million new cancer cases annually will be diagnosed. This will be primarily due to an aging population. Furthermore, the majority of these cases will occur in less developed regions of the world.

The American Cancer Society estimates that the global economic burden of cancer is in the region of $[redacted] annually. This is [redacted]% of worldwide GDP figures. The top cancers that contribute to this economic burden are lung, colorectal and breast cancer, costing over $[redacted], $99 billion, and $[redacted] respectively.

The National Institutes of Health (NIH) indicated that the economic burden of cancer in the US is over $[redacted], annually. This is divided into direct medical costs ($[redacted]) and indirect mortality costs ($[redacted]) that includes the cost of lost productivity.

Figure x: Top Three Cancers Leading to Global Economic Burden of Cancer ($ Billion)



1.3.5 How Cancer Biomarkers are Revolutionizing Cancer Treatment

Breast cancer and the use of Herceptin as treatment is an important example of how biomarker detection saves lives and money. Breast cancer is the second highest frequency of cancer globally with a reported 10.9% of total cancer diagnoses. Herceptin (trastuzumab, Genentech) was FDA approved for use in breast cancer patients in 1998 at a cost of between $[redacted] to $[redacted] annually. However, subsequent analysis indicated that Herceptin was only effective in 25-30% of women who's tumour cells over synthesized the protein human epidermal growth factor-2 HER2/Neu.

By 2006 all invasive breast cancer patients were recommended to take the HER2 genetic test to identify if they would respond to Herceptin treatment. A further breakthrough in 2008 occurred when a more efficacious Herceptin formulation was approved. Since 2010, more than 420,000 women have been treated with Herceptin, globally.

Today, over 1.7 million women are diagnosed with breast cancer annually (GLOBOCAN). This is a 20% increase in incidence since 2008 estimates, and 14% increase in mortality rates. In 2012 alone, 522,000 women died of breast cancer, compared to 458,000 deaths in 2008.

Early screening and a highly specific biomarker assay is important in detecting cancer, especially in colorectal and prostate cancers as early symptoms are negligible. The use of biomarker companion diagnostics will not only save payers money, it will also promote more targeted therapeutics – thus providing patients with personalized cancer treatment. This has the added benefit of being more effective and having lower adverse reactions and toxicity profiles. Overall, the use of oncogenic biomarker tests and targeted cancer therapies will revolutionize cancer treatment in the short and longer terms.

1.3.6 What are the most Significant and Strategic Cancer Biomarkers?

This cutting-edge report provides a wealth of information on the current and prospective biomarkers in the cancer field. A comprehensive array of the most significant oncogenic biomarker families are analysed with respect to their mechanism of action, clinical functionality and also current clinical trials and studies that are investigating the following:

- P53 Transcription Factor Oncogenic Mutations
- Epidermal Growth Factor Receptor (EGFR)
- BRCA- Mutant Breast and Ovarian Cancer biomarkers
- PARP-Inhibitors
- PTEN – the Tumour Suppressor Gene
- Ataxia Telangiectasia Mutated (ATM)
- TMPRSS2-ERG
- MiR-17/92 Cluster
- Significant Molecular Targets of MiR-17/92

A number of cancer types have developed resistance to targeted therapies, and so this report also identifies current strategies to defeat resistance in certain biomarker types.

1.3.7 Global Biomarker Test Market Analysis

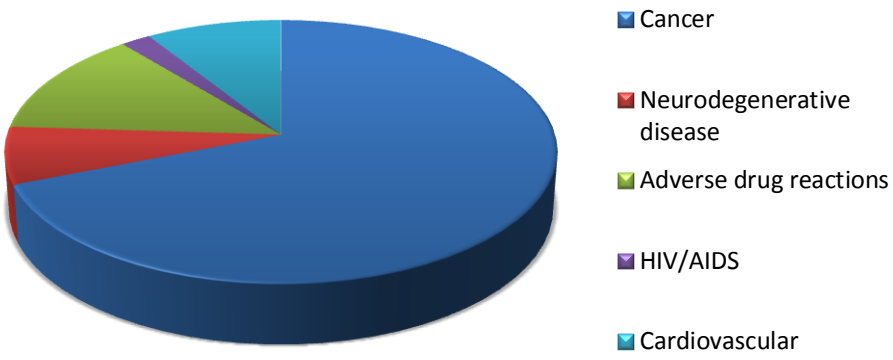
Kelly Scientific Publications estimate that the global biomarker market is currently worth $[redacted] up from $[redacted] in 2012. Over the last number of years it has grown at a CAGR of [redacted]%, however this is expected to rise to [redacted]% between 2013 and 2018. By 2018, the global biomarker market is estimated to be worth over $[redacted].

The global biomarker market is segmented into the following therapeutic areas:

- Oncology
- Cardiology
- Neurology
- Infectious disease (e.g., HIV, TB)
- Renal disorders
- Diabetes
- Arthritis

Detailed analysis of this market is provided within this report. The cancer biomarker market is by far the most established within the biomarker space.

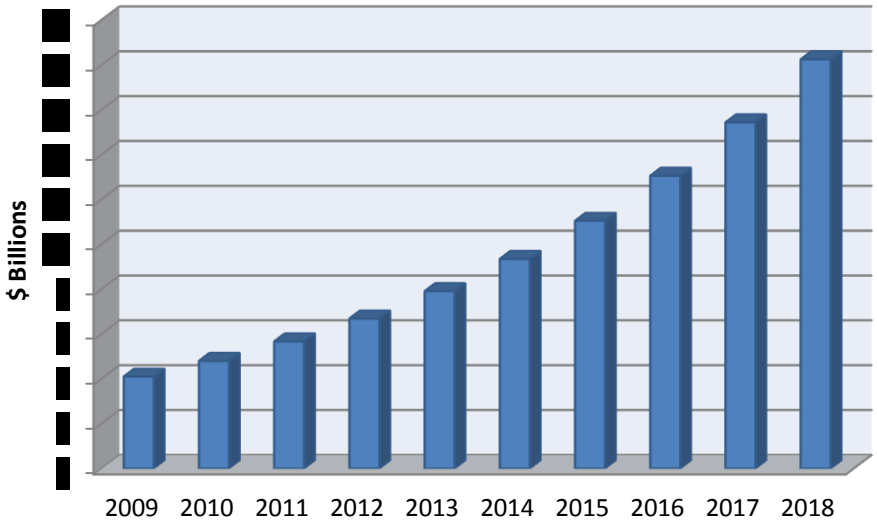
Figure 2: Oncogenic Biomarker Share of Total Personalized Medicine Biomarker Space



1.3.8 Global Cancer Biomarker Market Analysis

As early as 2009, the global cancer biomarker market was worth $[redacted] and grew to $[redacted] in 2013 with a CAGR of [redacted]%. Over the next five years the market is expected to grow further, by a CAGR of [redacted]% to reach over $[redacted] in 2018. It is estimated that by 2018, 30% of cancer patients will have a predictive biomarker assay. Currently, 22% of pipeline therapeutics are being investigated in a subsection of patients defined by using a biomarker assisted assay. The cancer biomarker market has the largest share of the overall biomarker market at [redacted]% in 2013 ($[redacted] of $[redacted] total). By 2018, the oncology biomarker market is expected to be worth $[redacted], compared to $[redacted] in total.

Figure 4: Global Cancer Biomarker Market Worth (Billions) and CAGR (%) 2009-2018



There is considerable growth within the oncology biomarker market ([redacted]%) due to a number of reasons including:

- Rising prevalence of cancer rates globally
- Increased emphasis on early diagnosis
- Enhanced testing capabilities
- Increased awareness and uptake of high-throughput technologies
- Significant advancements in biomarker research
- Increase in number of targeted oncology therapy clinical trials
- US government initiatives
- Increased healthcare professional awareness
- Increased patient awareness
- Strength of the personalized medicine market
- Strength of the overall biomarker market

This report gives a full analysis of the above points and analyses how they will affect the market. In the near future, the oncology biomarker testing market will see the introduction of new assays entering the space. This is primarily due to the fact that technologies such as next generation sequencing will become more cost effective and affordable. Out-licencing and also the co-development of therapy-specific companion diagnostics will promote the market further. Initially, these assays require high levels of healthcare professional interpretation and they are complex to carry out, however over time these restraints will decrease and targeted biomarker evaluation will be more significantly integrated into the healthcare system

1.3.9 Oncology Biomarker Market Main Industry Players

Competitor analysis of the main and upcoming market players is also included in this detailed report. We include up-to-date financial and business strategy analysis for each company, and also detail of every oncology biomarker assay that they provide. Pipeline portfolios are also included, as are current clinical trials, FDA approvals, business collaborations and mergers. The following companies have been analysed by experts at Kelly Scientific Publications:

- 23andMe
- Affymetrix
- Ambry Genetics
- Astex Pharmaceuticals
- Atossa Genetics
- BioMerieux
- CuraGen
- Celera Corporation (Quest Diagnostics)
- Celldex Therapeutics
- deCode Genetics (Amgen)
- Foundation Medicine
- Illumina
- Genelex
- Genomic Health

- Myriad
- Nodality
- Randox
- Qiagen

1.3.10 Drivers, Restraints, Opportunities and Challenges of the Cancer Biomarker Market

This analyses also provides you with a comprehensive account of the drivers and restraints of the global and US cancer biomarker markets. There is a general high demand for biomarker assays and corresponding targeted therapeutics and also an un-met need in the market space. Clinical trials are supporting market growth as they are more streamlined and increasing FDA and regulatory support is also proving positive. There has been a significant boost in oncogenic biomarker research publications over the last five years, and this is further enhancing R&D budgets and investment opportunities. A number of restraints such as initial investment, sample collection and storage and also regulatory hurdles were also identified. The cancer biomarker market however, has enormous potential not only within the overall biomarker space, but also within the personalized medicine and companion diagnostic markets.