Oncology Biomarker Market Size, Growth and Trends (2017-2020)

DECIBIO
DECISIVE BIO-INSIGHTS

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1st edition

Agenda

We forecast that the oncology biomarker market will reach ~$3.7B in 2020, growing at ~11% p.a. from ~$2.7B in 2017 driven by the global personalized medicine initiatives and increased patient access to biomarker tests (1 of 2)

Abstract

Personalized medicine continues to transform the field of clinical oncology across the spectrum of patient care. Oncology biomarker testing is now used for applications including treatment selection, prognosis, and monitoring drug response / tumor progression. We forecast that the cancer biomarker testing market size will grow at ~11% p.a. from ~$2.7B in 2017 to ~$3.7B in 2020. The near-term growth is driven primarily by the global personalized medicine initiatives and evolving regulatory and reimbursement landscapes in the U.S. that are designed to make biomarker-based diagnostic tests more accessible to patients. While treatment selection is the most established application within oncology biomarker testing, advances in technology and increasing shift of focus to blood-based biopsies are expected to continue to drive developments in other areas of unmet needs such as screening and early detection of cancer.

The first edition of this report reviews the market size, segmentation, growth and trends of the oncology biomarker test manufacturer / provider (i.e., excluding instruments and service fees associated with labor and shipping) market. We assess the oncology biomarker testing market across 4 segments:

- Technology: Immunohistochemistry (IHC), ISH/FISH/CISH, PCR/qPCR/dPCR, Sanger sequencing/CE sequencing Flow cytometry, ELISA, NGS, and others***
- Indication: Breast cancer, Lung cancer, Prostate cancer, Colorectal cancer, Pan-cancer, and others
- Regulatory status: In vitro diagnostics (IVD), Lab developed tests (LDT)
- Geography: U.S., Europe, Japan, Asia/Pacific, and Rest of the world (RoW)

For each of these segments, we provide the market size and growth from 2017 to 2020, as well as commentary on key growth drivers and moderators.

Major factors driving future growth include:

- Increased adoption driven by guideline inclusions (e.g., NCCN, ACP, NICE) and growing evidence of clinical utility
- Increased number of diagnostic-enabled immuno-oncology drugs and targeted therapies
- Increased pharma spending on companion diagnostic test commercialization
- Evolving regulatory framework for NGS-based comprehensive tumor profiling tests
- Evolving Medicare coverage landscape broadening patient access to NGS-based tests
- Shift towards more expensive multiplex panels from low-cost, single-gene tests
- Increased adoption of liquid-biopsy assays to track and monitor drug response
- Growing role of personalized medicine outside the U.S., particularly in Japan and China

Source: DeciBio analysis

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Abstract

Key factors moderating growth including:

- Reimbursement uncertainty and pushback on the commercial payor front limiting access to NGS-based diagnostics
- Lack of concordance across tests (e.g., cutoff values), rendering it difficult to use results from one test across drugs
- Under-implementation of biomarker testing given the lack of guidance and difficulty with navigating through new developments
- Resistance to adopting or shifting to new technologies (e.g., liquid biopsy)
- Bioinformatics and data analysis challenges, especially for translating sequencing data into therapeutic decisions

We also review interesting market trends, such as:

- Increased uptake of I/O markers, such as PD-L1 and MSI; TMB will likely be among the next wave of I/O markers
- Increased use of comprehensive genomic profiling tests in I/O clinical trials, particularly as pharma companies try to move beyond a simple PD-L1 monotherapy
- Growth in emerging applications, such as resistance monitoring and minimal residual disease (MRD) monitoring
- Increasing number of test developers seeking an IVD status for their NGS tests via the new 510(k) clearance pathway
- Increasing number of proprietary service providers working on kit developments as a way to gain access to decentralized markets, such as Germany and France
- Growing number of U.S. companies forming partnerships with Chinese companies as an entry into the Chinese market
- Continued flow of funding into early cancer detection efforts, which holds the greatest opportunity for growth in the long-term
- Increased interest in tissue-agnostic, biomarker-driven indications with markers that work across multiple cancer types

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This report is divided into the following sections

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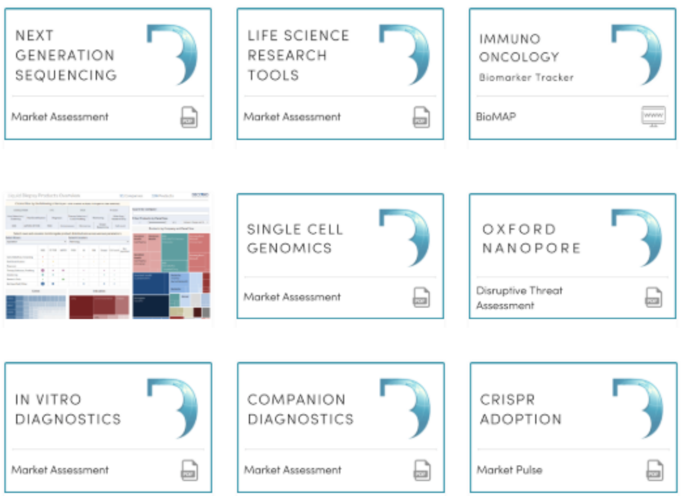

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- DeciBio provides expert opinions on where the market is headed and why
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We developed this report assembling a team of experts in this space (2 of 2)

About the Authors

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At DeciBio, Dr. Aijian has worked on several engagements, covering all types of therapeutic areas and diagnostic technologies. In these projects, Andrew has lead extensive secondary and primary research campaigns, developed bottom-up and top-down market models, constructed NPV forecasts, and evaluated customer feedback and market potential for client product profiles.

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As a Market Research Associate at DeciBio, Jessica has authored multiple market research reports, covering a wide variety of topics in the life sciences space including, single cell genomics, life science research tools, and cancer diagnostics. As part of the data product team at the firm, she is currently working to develop competitive intelligence data analytics solutions.

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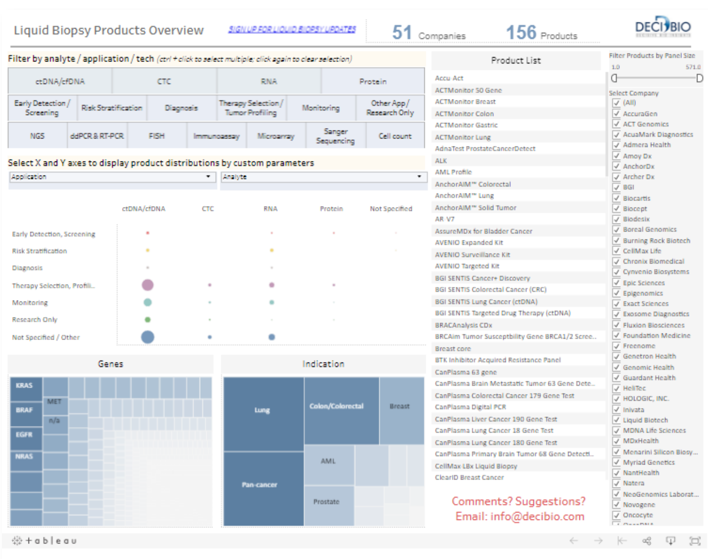

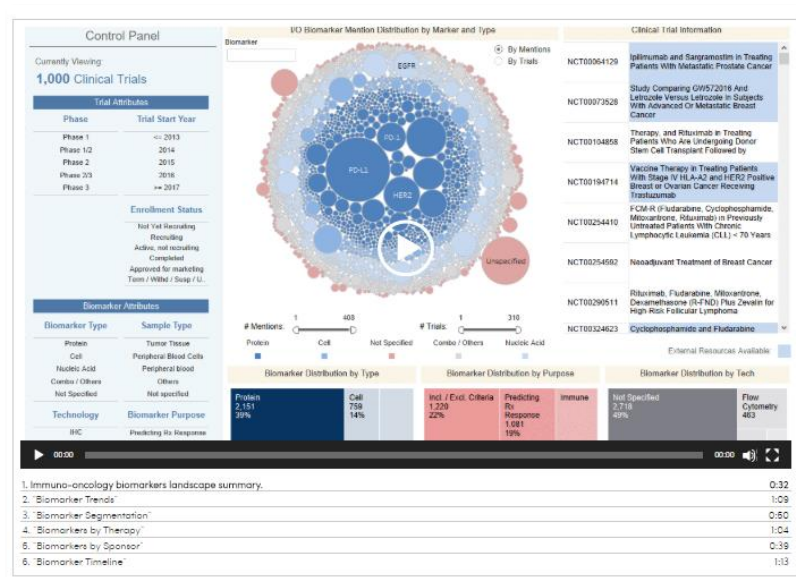

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