Biomarker Testing In Oncology

Biomarkers are indicators of a patient's likelihood to respond to certain treatments. By testing for predictive biomarkers, Oncologists can make more informed treatment decisions.

The current clinical picture

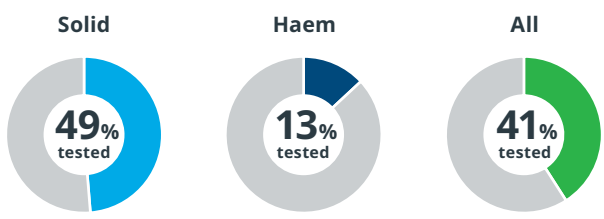
The use of biomarkers in oncology has been growing since the first wave of targeted therapies in the late 1990s, which included Gleevec (Acute Lymphoblastic Leukaemia, ALL) and Herceptin (Breast Cancer). Solid cancer patients see higher testing rates than haematological (haem) cancer patients, as a smaller number of predictive biomarkers linking to targeted therapies have been identified for haem cancers. We see greater evolution of testing within certain indications with high incidence and high unmet need. Solid cancers which show high uptake of several different biomarker tests are Breast Cancer and Non-Small Cell Lung Cancer (NSCLC). Certain haem cancers show high testing rates for fewer key biomarkers, such as ALL and AML.

Testing rates by biomarker

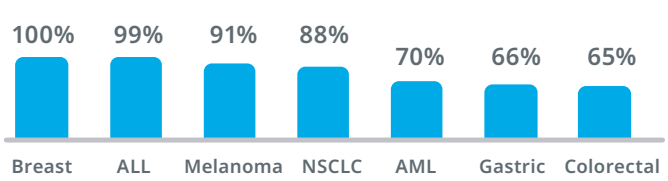
BRAF in Melanoma patients	**98%**	**93%**
HER2 in Breast Cancer patients	**97%**	**98%**
EGFR in NSCLC patients	**79%**	**79%**
PD-L1/2 in NSCLC patients	**82%**	**75%**
KRAS in Colorectal Cancer patients	**92%**	**60%**

Source: IQVIA Brand Impact, 2018, and IQVIA Oncology Dynamics, MAT Q1 2019

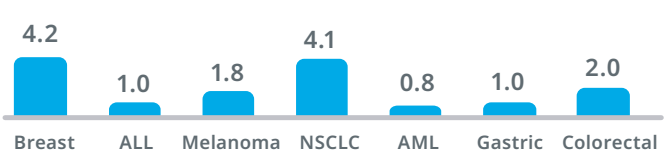
Percentage of patients tested for any predictive biomarker



Top indications by percentage of patients tested for any biomarker



Average number of biomarker tests per patient

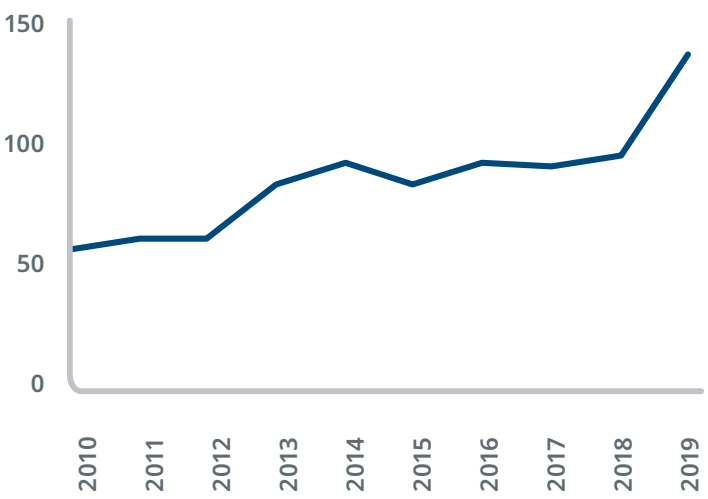


Source: IQVIA Oncology Dynamics, MAT Q1 2019

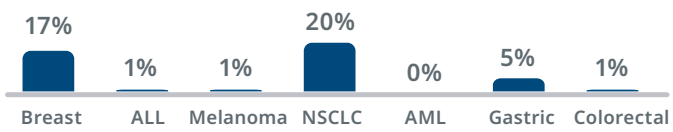
The future

Late-stage biopharmaceutical pipelines are increasingly populated with targeted oncology products which require biomarker testing. The share of trials with biomarkers has increased from a third to half of all oncology Phase III trials in the past decade. Breast Cancer and NSCLC are dominant indications in Phase III clinical trials, reflecting the high clinical frequency of biomarker testing in these indications. An increasing share of the predictive biomarker Phase III pipeline is occupied by Ovarian Cancer and Prostate Cancer trials (6% and 4% respectively in 2019), driven by the success of PARP Inhibitors.

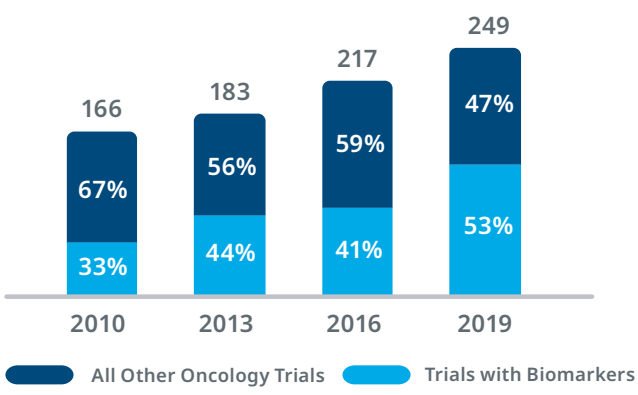
Count of Phase III industry oncology clinical trials with predictive biomarkers



Biomarker trials Phase III share, 2019



Phase III industry oncology clinical trials



What does this mean for targeted therapies

20 years on from the first wave of targeted therapies, biomarker testing has become effectively mandatory in certain indications. However, the goalposts are moving as increasing numbers of biomarkers are identified and oncologists are faced with increasingly complex choices. It will become harder to drive successful adoption of new biomarkers.

98%

The success of HER2+ targeted therapy Herceptin followed by a franchise of products has led to **98%** of Breast Cancer patients to be tested for HER2.

96%

96% of ALL patients are tested for the Philadelphia chromosome. This is due to the success of tyrosine kinase inhibitors that target the Philadelphia translocation (e.g. Gleevec).

Successful adoption of targeted therapies is not possible without successful adoption of their associated biomarker tests into clinical practice.

Regulatory bodies are encouraging co-development of companion diagnostics and targeted therapies rather then having them "come together superficially towards the end". (EMA, 2017)

Products shape treatment. Successful therapies dictate the clinical adoption of predictive biomarker testing, and the segmentation of major tumour types.

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IQVIA European Thought Leadership Analysis.

Sources: IQVIA Oncology Dynamics (Includes Germany, Spain, UK, France, Japan, Korea, China); IQVIA Brand Impact (US only); ClinicalTrials.Gov

Glossary: ALL = Acute Lymphoblastic Leukaemia; NSCLC = Non-Small-Cell Lung Cancer; AML = Acute Myeloid Leukaemia; Haem = Haematological.