

Biomarker Testing in Clinical Trials



Biomarker testing is the analysis of a patient’s tissue, blood, or fluid biospecimen for the presence of a biomarker that can provide insight into diseases like cancer¹. Information gained from biomarker testing can then be used to help guide medical treatment, often called precision medicine. By identifying biomarkers, patients can receive treatments that may not otherwise be considered for their disease or cancer.

Importance of biomarker testing:

- Recent studies show that biomarker testing may improve outcomes for patients with hard-to-treat cancer types such as digestive cancers, lung, and breast.²
- Nearly 60% of all cancer drugs approved in the last 5 years require or recommend biomarker testing before use.³
- Biomarkers may guide doctors’ treatment decisions by providing clues about whether patients will respond to standard treatment options.⁴

The number of targeted therapies that require biomarker testing is increasing rapidly and cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies.

What are clinical trials?

Clinical trials are a key step in advancing potential new cancer treatments from the research setting to the cancer care clinic and give patients the opportunity to access the latest developments in treatment and access to care that is equivalent to treatment outside of a trial. Patient participation in trials is crucial to their success.

Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies. Biomarker testing can identify patients who are eligible for these trials. For example, after biomarker testing, a patient may find that their cancer has biomarkers that are not well understood or lack a corresponding targeted therapy. However, they may find that their test results make them eligible for a clinical trial of an investigational targeted therapy.

How has biomarker testing impacted clinical trials?

- The number and percentage of cancer clinical trials that involve biomarkers has grown significantly, from 15 percent in 2000 to 55 percent in 2018.⁵
- In clinical trials, patients whose cancer care was based on biomarker testing had a better response to treatments than those without biomarker testing.^{6,7}
- In a study on pancreatic cancer, patients receiving targeted therapies following biomarker testing lasted twice as long on treatments without disease progression.⁸

Biomarker testing is becoming increasingly important for new targeted therapies. However, access to appropriate biomarker testing can still be a challenge for patients. By working to remove these barriers, we can ensure more patients receive the best care for their specific cancer.

Learn more at www.fightcancer.org/biomarkers.

¹ NCI Dictionary of Terms. <https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatmen>. Accessed August 16, 2021.

² Massard C, Michiels S, Ferte C, et al. High-Throughput Genomics and Clinical Outcome in Hard-to-Treat Advanced Cancers: Results of the MOSCATO 01 Trial. *Cancer Discovery*. 2017;7(6):586-595.

³ Global Oncology Trends 2021. IQVIA Institute; June 2021.

⁴ Devarakonda S, Govindan R. Biomarker-Driven Staging—Are We There Yet? *JAMA Network Open*. 2019;2(12):e1917052-e1917052.

⁵ https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/The_Evolution_of_Biomarker_Use_in_Clinical_Trials_for_Cancer_Treatments.pdf

⁶ Massard C, Michiels S, Ferte C, et al. High-Throughput Genomics and Clinical Outcome in Hard-to-Treat Advanced Cancers: Results of the MOSCATO 01 Trial. *Cancer Discovery*. 2017;7(6):586-595.

⁷ Schwaederle M, Zhao M, Lee JJ, et al. Association of Biomarker-Based Treatment Strategies With Response Rates and Progression-Free Survival in Refractory Malignant Neoplasms: A Meta-analysis. *JAMA Oncology*. 2016;2(11):1452-1459.

⁸ Pishvaian MJ, Blais EM, Brody JR, et al. Overall survival in patients with pancreatic cancer receiving matched therapies following molecular profiling: a retrospective analysis of the Know Your Tumor registry trial. *The Lancet Oncology*. 2020;21(4):508-518.