White paper

Cerba Research

Measurable Success:

The Value of Biomarkers from Discovery Through Commercialization

Revised November 2025

The Authors

Rania Gaspo, B.Pharm. Ph.D.
Director, Global Therapy Area Lead

Lorella Di Donato
Chief Laboratory
& Operations Officer

Why do some patients respond to therapy while others do not? The answer can be found in the concept of biomarkers: objective, measurable indicators of the presence or severity of disease. Used for decades to aid medical diagnosis, researchers today use biomarkers in every phase of drug discovery and development.

There's good reason. Biomarkers can triple drug development success rates, accelerating the availability of new therapeutics.[1] A biomarker-driven approach provides multiple benefits, including:

- Enable early proof-of-concept studies for novel therapeutic targets, reducing drug attrition rates
- Predict drug efficacy more quickly than conventional clinical endpoints
- Stratify patients during enrollment with more accuracy, hence reducing the number of patients needed to show clinical benefit
- Use as surrogate endpoints in clinical trials
- Help determine benefit-risk profile, to facilitate and smooth regulatory decisions

A recent increase in biomarker development parallels both the rise in precision medicine and advances in science and technology. Precision medicines require predictive biomarkers to classify patients by disease risk and prognosis, as well as to identify patients more likely to respond to therapy or to develop side effects.

Meanwhile, as genetic sequencing, diagnostic testing, and other technologies have advanced and become more cost-efficient, scientists have focused on genetic biomarker candidates. Combined with biomarker development based on components circulating in blood, as well as proteins residing in tissue which are identified through imaging, the number of circulating biomarkers we test for has grown tremendously. The challenge with all this discovery lies in validating biomarkers to confirm their clinical or predictive significance. That's where Cerba Research steps in.