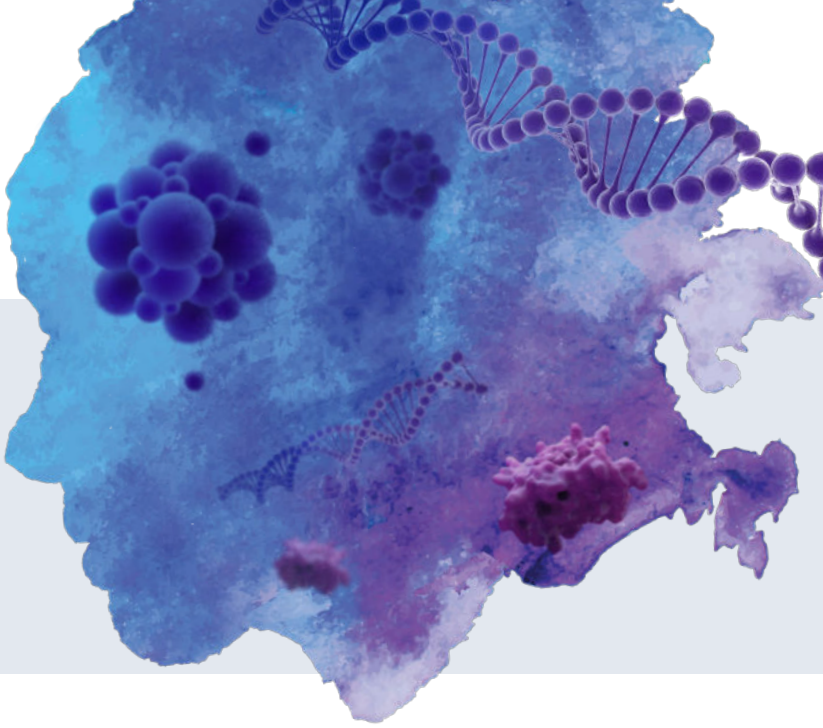
Cerba Research



Measurable Success:
The Value of Biomarkers From Discovery Through Commercialization

Jerome Sallette, Chief Scientific 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. 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.

Our Approach

Cerba Research partners with clients to develop a robust biomarker validation process to help increase the success of biomarker integration in clinical development. That process starts with analyzing specificity during prevalidation and continues through preclinical, clinical, Clinical Laboratory Improvement Amendments (CLIA), and FDA validation.

Cerba Research has adapted to clinical research complexities and the rise of more targeted therapies with forward-looking solutions. We can apply traditional and newer ELISA platforms as well as ultra-sensitive detection capabilities, including single and multiplex analysis, in various disease categories.

Meanwhile, the Cerba IVD team continually custom-evaluates and validates new biomarkers to help clients move closer to breakthrough treatments. Expertise ranges from routine clinical biology and esoteric testing to specimens and data sourcing.

Accessing qualified specimens from millions of patients in our clinical pathology labs, and using this data prospectively, helps us validate new drugs and new biomarkers, as well as helps our clients recruit patients for their trials. We continually onboard new technologies and make wise use of data science to generate more insights and relevance to biomarkers.

None of this happens, however, before learning all about a client's products and their goals. During those preliminary discussions, we help refine tests and methodologies used and propose alternatives that could

yield more precise results. At the same time, we're willing to add or remove tests based on client feedback. Development is a true team effort.

Advances in Biomarker Development

Biomarkers can be individual genes or proteins, multi-gene or protein panels, biomolecules, or even microbiota from the gut microbiome.

Cerba Research is fortunate to have skilled scientists with experience validating and testing these and other types of biomarkers. Our methods include, but are not limited to, flow cytometry, tissue immunohistochemistry (IHC), multiplex IHC, PCR, NGS, and cytokine and circulatory protein analysis, among others. This depth of experience enables us to develop and validate both off-the-shelf and novel biomarkers.

Our scientists team up with skilled researchers and physicians — experts who are treating patients every day — through partnerships with pathology and genomics labs, startups, and academia. With all these experiences and techniques under one roof, clients receive comprehensive insights more efficiently.

The Importance of a Global Network

Delay when transporting specimens introduces risk of variability. To serve clinical research on a global level requires a network of instruments, platforms, and experts, with the ability to centralize the analysis and review data. Cerba Research developed a global footprint to accommodate testing for research centers worldwide.

Consistent sample handling ensures the quality of samples remains intact throughout the journey. Access to more than 700 labs and blood collection sites within the Cerba HealthCare Group, anchored by seven offices across five continents, allows Cerba Research to store specimens close to research sites while providing global logistics to and from our client's sites and data analysis. To operate both globally and locally requires world-class logistics. The result is minimized risk for our clients. Also, by analyzing samples quickly, clients are ensured the highest quality data.

Close Communication, Scientist to Scientist

A global network of labs also means access to a broad range of skilled laboratory researchers. In many cases, clients want to validate new tests or testing modalities. Cerba Research excels in developing and validating customized assays. However, whether we provide custom solutions or biomarkers from our vast portfolio depends on the outcome of an in-depth scientist-to-scientist discussion — between your experts and ours.

We are keen to open the dialog and our agile nature adjusts to clients' requirements. For example, if you are developing a biomarker-guided oncology trial and have a clear idea of your needs, we accommodate, offering suggestions where they bring value. If you have open-ended questions about biomarker development and validation, we bring in technical, medical, and pathology experts to develop a solution. We remain as flexible as possible while designing a solution grounded in science.

Your Partner From Early Research Through Clinical Trials

This level of close communication may start in drug discovery, but it continues through to commercialization. We assist in development and validation from nonclinical through to Phase I-III clinical trials. Our biomarker and companion diagnostic services operate in continuum, allowing you to fully optimize R&D productivity.

As clinical research becomes more biomarker-driven, the demand for companion diagnostics and results has increased. The therapy and the test must be addressed concurrently. To do so, Cerba Research calls upon its diagnostics business unit, which focuses on benchmark validation of new devices, reagents and biomarkers, and provides qualified — and often rare — specimens. Thanks to the network of Cerba HealthCare diagnostics labs, we also make sure those tests will be routinely available to be accessed by patients when the drug is on the market.

When combined with our central laboratory solutions (specialty lab, FCM, ICH, NGS, BioA, metabolomics), additional translational science (CDx, biobanking), and IVD (biospecimens, prospective sample collection, IVD evaluation), clients gain additional value. Working with one vendor throughout drug development lowers risk by eliminating transfers, as well as improves administrative and operational efficiency: one vendor, one contract, one point of communication for multiple services.

The Road Ahead

Given the promise of precision medicine to treat debilitating disease more effectively, we expect it to remain a focus of clinical research for the foreseeable future. As science and technology advance, Cerba Research will be here to provide comprehensive biomarker services, doing our part to change the shape of your clinical development.