

## Blood-based Biomarkers and the New Landscape of Alzheimer's Research

01 December 2025 | Opinion | By Dr Michael Miller, Chief Operating Officer, Quanterix, USA

**Story of blood-based biomarkers is a convergence of biology, technology, and shared commitment**



For much of the past century, Alzheimer's disease has been one of medicine's most daunting frontiers—biologically complex, devastating in impact, and difficult to diagnose early. Conventional diagnostic methods like positron emission tomography (PET) imaging and cerebrospinal fluid (CSF) analysis offer precision but remain invasive, costly, and logistically challenging, especially in low- and middle-income regions.

That is now changing. Ultra-sensitive, blood-based biomarkers are transforming how clinicians and researchers detect, monitor, and study Alzheimer's. These advances are reshaping diagnostics and collaboration between the public and private sectors to speed up drug development and scale innovation.

### **Reimagining Diagnosis: From Complex to Accessible**

Blood-based biomarkers—like p-tau217, p-tau181, A $\beta$ 42/40 ratios, NfL, and GFAP—enable Alzheimer's pathology measurement with a simple blood draw. The availability of clinically validated blood tests are changing how clinicians diagnose and treat Alzheimer's disease and how clinical trials are designed. Furthermore, researchers are evaluating blood tests that may identify disease progression years before symptoms, potentially allowing health systems to extend early detection from tertiary care to primary and community settings.

Globally, this could help expand access for disease detection and management. Many countries face rapid ageing, increased rates of dementia, and limited access to imaging. Blood tests offer a scalable, cost-efficient way to expand early detection and better allocate specialist resources. Tests that combine multiple biomarkers in a single blood draw, such as Quanterix's LucentAD Complete—which measures five AD biomarkers simultaneously—further democratise the process. Over time, this

could help reduce diagnostic disparities linked to income and geography.

These same biomarkers are changing drug development. In clinical research, they help reduce imaging needs, monitor responses to therapy, and enable adaptive trials.

This approach accelerates discovery and approval. Researchers can now track molecular changes indicating true disease modification, not just late-stage cognitive outcomes. As combination therapies and precision neurology emerge, these insights will be essential for selecting patients and optimising trial success.

### **Public Science, Private Scale**

Government-funded initiatives have long built the foundation for Alzheimer's research—such as NIH cohort studies in the U.S. and efforts in Japan, Korea, China, and Singapore. These projects built the datasets and insights essential to today's biomarker development.

Now, as government research budgets shrink and approval processes shift, the private sector is taking a larger role in translational science. Pharmaceutical and diagnostics companies, as well as laboratories, increasingly partner to validate assays, set reference standards, and advance the clinical readiness of tests.

This shift creates a new balance: the public sector generates knowledge and long-term data, while industry supplies speed, capital, and technical infrastructure to turn that knowledge into patient-ready solutions. When coordinated, these strengths can move research to patient care more quickly than ever.

### **Ensuring Access and Sustainability**

To fulfill their promise, blood-based biomarkers must remain accessible and sustainable in healthcare systems. Reimbursement and pricing are persistent global challenges. In 2024, the U.S. Centers for Medicare and Medicaid Services proposed reimbursement levels for AD biomarkers that many labs called unsustainable, highlighting a bigger issue: the economic model for next-generation diagnostics still lags behind their clinical value.

Policymakers, payers, and industry must align on frameworks that acknowledge the cost savings of earlier diagnosis and optimised treatment. Demonstrating that biomarker results alter decisions and outcomes will be key to securing coverage. Harmonised standards, quality controls, and international collaboration will ensure tests work reliably across regions and populations.

### **Collaboration as the Constant**

The story of blood-based biomarkers is a convergence of biology, technology, and shared commitment. Public research lays the foundation; private enterprise scales innovation. Both sectors transform discovery into diagnostic products, leading to better patient outcomes.

In Alzheimer's and beyond, biomarkers let us detect disease earlier and act sooner. Sustaining progress requires ongoing collaboration across borders, sectors, and disciplines. With thoughtful investment and equitable access, blood-based diagnostics can move from promise to practice and redefine brain health.

Dr Michael Miller, Chief Operating Officer, Quanterix, USA