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Biomarkers: Finding a Test for <INSERT> Disease

What Are Biomarkers?

A diagnostic biomarker is a measurable characteristic in the body associated with the presence of disease. Blood sugar level is a diagnostic biomarker of diabetes; levels of 6.5 percent or higher on two separate tests indicate disease.

A progression biomarker is a measurable characteristic in the body that changes over time in a way that can be linked to disease progression. This type of biomarker is critical for clinical trials

— particularly trials of treatments to prevent, slow or stop disease — to objectively measure whether the drug is working. White blood cell count is a progression biomarker of leukemia; rising levels show the condition is getting worse, while a count moving toward normal shows improvement.

There is currently no way to stop <INSERT>

disease. A diagnostic biomarker would allow us to identify people with<INSERT>— and intervene — earlier, maybe even before symptoms appear.

<INSERT> clinical trials are frequently inconclusive and take a long time.

> With no diagnostic biomarker, some<INSERT> trial enrollees may not have <INSERT> pathology, confusing results.

> With no progression biomarker to track the disease, there is no way to objectively measure treatment effects. Most trials use some <INSERT>,

to determine whether a treatment is working. But these methods are subjective, and symptoms can vary day to day, even hour to hour. These less-than-optimal measures may have contributed to a history of inconclusive trial results. They also mean trials often require more time and volunteers.

Some companies may not be interested in making <INSERT> drugs. Given the time, cost and uncertainties, <INSERT>trials are highly risky for drug makers. Fewer companies working on <INSERT>may mean fewer new therapies.

Why Are There No Biomarkers of <INSERT> Disease?

There are a few advanced <INSERT> techniques (e.g., that can help researchers measure<INSERT> in its earliest stages, but no widely available and affordable biomarker tests have been conclusively validated. The variation in <INSERT> from person to person, and the complex nature of brain diseases, present challenges in finding and validating<INSERT> biomarkers.

How Does the Lack of Biomarkers Affect People with <INSERT> diagnosis is subjective, based on observing and rating symptoms. This translates to a high rate of misdiagnosis and non-optimized care. A diagnostic biomarker would help people name their disease, watch for symptoms and start treatment.