

# Biomarkers: Finding a Test for Parkinson's 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.

## Why Are There No Biomarkers of Parkinson's Disease?

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

## How Does the Lack of Biomarkers Affect People with Parkinson's?

Parkinson's 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.

There is currently no way to stop Parkinson's disease. By the time the first symptoms show, as many as 60 to 70 percent of a person's dopamine neurons may have degenerated. A diagnostic biomarker would allow us to identify people with PD — and intervene — earlier, maybe even before symptoms appear.

PD clinical trials are frequently inconclusive and take a long time.

- > With no diagnostic biomarker, some PD trial enrollees may not have Parkinson's pathology, confusing results.
- > With no progression biomarker to track the disease, there is no way to objectively measure treatment effects. Most trials use some form of symptom assessment, such as the Unified Parkinson's Disease Rating Scale (UPDRS), 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 Parkinson's drugs. Given the time, cost and uncertainties, PD trials are highly risky for drug makers. Fewer companies working on PD may mean fewer new therapies.

## What Can I Do to Help Identify a Parkinson's Biomarker?

Register for Fox Trial Finder, The Michael J. Fox Foundation's online clinical trial matching tool that connects volunteers to the studies that need them. Visit [www.foxtrialfinder.org](http://www.foxtrialfinder.org) to register.

