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First-of-its-kind Parkinson's biomarker guidelines invigorates drive for treatments

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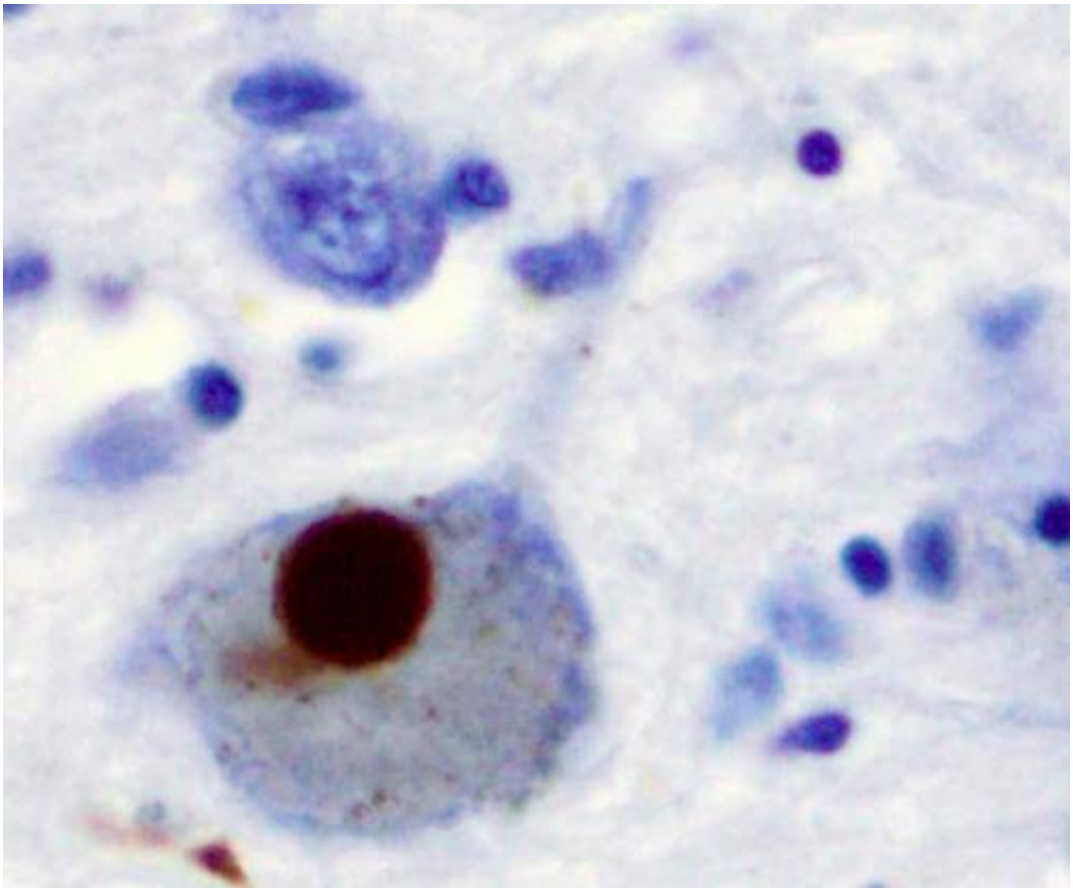

Immunohistochemistry for alpha-synuclein showing positive staining (brown) of an intraneural Lewy-body in the Substantia nigra in Parkinson's disease. Credit: Wikipedia

Parkinson's disease affects more than 4 million people worldwide, with

numbers projected to double in the next few decades. With no known cure, there is a race for treatments to slow or stop the progression of the disease. Key to the research and discovery of treatments for Parkinson's is the identification of biomarkers—a measureable biological indicator, such as proteins found in blood, which can help diagnose disease.

Today, a slate of guidelines to shape the future of Parkinson's biomarker research have been published in *Science Translational Medicine*. While previous recommendations have been created to support the research of Parkinson's biomarkers, this is the first developed in collaboration with institutions outside of academic medicine, including The Michael J. Fox Foundation for Parkinson's Research.

Biomarkers can not only help predict, diagnose, or monitor disease, but they can also be used to see how well the body responds to a treatment for a disease or condition. For example, within Alzheimer's disease, measures of the protein beta-amyloid help diagnose the disease, and also serve as a drug target in clinical trials. Similarly, measuring cholesterol levels can help with the diagnosis and treatment of cardiovascular disease.

Lead author Alice Chen-Plotkin, MD, the Parker Family Associate Professor of Neurology in the Perelman School of Medicine at the University of Pennsylvania, led the project in partnership with experts from 36 organizations, including government groups, academic institutions, and non-profit funding agencies, to foster collaboration and discovery of these critical biomarkers.

"These players at times have acted in separate worlds, but with a disease affecting so many and lacking in disease-modifying therapies, we're coming together for essential collaboration and innovation," Chen-Plotkin said. "Biomarkers to bolster our efforts to develop new therapies are urgently needed. These guidelines can help make the discovery of

biomarkers for Parkinson's a reality."

The guidelines focus on three areas—recommendations for types of biomarkers researchers should identify in order to aid the development of new treatments, resources for collaboration, and research principles to follow.

Previous research efforts have largely focused on biomarkers that distinguish Parkinson's disease from healthy individuals or those with other neurodegenerative diseases such as Alzheimer's disease. However, these guidelines argue for a shift to focus on biomarkers that look within Parkinson's disease itself, as there are many ways the disease manifests in patients. This is an important element for planning clinical trials and developing new treatments.

Researchers have already built an ecosystem of biobanks at different centers across the world, which hold thousands of biological samples including blood and tissue. These biobanks hold many clues that could help propel the next breakthroughs in the treatment of neurodegenerative diseases, and the guidelines list recommended biobanks as a resource for researcher collaborations.

"Before the advent of these shared biobanks, investigators depended on their own ability to collect hundreds or thousands of samples for testing, preventing potential researchers lacking access to large clinical populations from entering the biomarker discovery arena," said Chen-Plotkin. "However, within the last five years, multiple public-private efforts have laid the groundwork for investigators from both academic and industrial sectors to access well-documented clinical samples. These repositories are all open for collaboration to improve the pipeline to take Parkinson's biomarkers from concept to clinic."

The guidelines also include recommendations for biomarker research

standards, such as larger sample sizes and replication across multiple patient groups. These principles will harmonize findings, streamlining and advancing the biomarker discovery process.

Ideas in the new paper originated from a Biomarkers Discovery Workshop convened by The Michael J. Fox Foundation in New York in March of 2016. They were further developed in discussions at the National Institute of Neurological Disorders and Stroke Parkinson's Disease Biomarkers Program annual meeting in Washington, DC, in August, 2016.

More information: A.S. Chen-Plotkin at University of Pennsylvania in Philadelphia, PA el al., "Finding useful biomarkers for Parkinson's disease," *Science Translational Medicine* (2018). stm.sciencemag.org/lookup/doi/ … scitranslmed.aam6003

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