

# Poster Session

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The Michael J. Fox Foundation

Advocate for Parkinson's Policy

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# Poster Session

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## Jeffrey Hausdorff, PhD

Professor, Faculty of Medicine and School of Neuroscience, Tel Aviv University  
Director, Center for the Study of Movement Cognition, and Mobility, Tel Aviv  
Sourasky Medical Center Tel Aviv Medical Center

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Jeffrey Hausdorff, PhD, and the research team that he leads aim to better understand, evaluate, and treat alterations in gait and balance that are associated with aging and disease. Hausdorff studies gait, balance, motor control and brain function, with a special focus on gait variability, wearable devices, freezing of gait, falls and Parkinson's disease. His cutting-edge research in this area has been funded by the National Institutes of Health and by private agencies and has been widely recognized. In 2013, he received the Gerontology Society of America's Excellence in Rehabilitation of Aging Persons Award, and in 2023, he was awarded the Aufzien Foundation Prize for established researcher in Parkinson's disease. His publications have been cited more than 83,000 times, placing him among the more influential scientists.

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## Abstract

### A Machine Learning Contest to Automatically Detect Freezing of Gait: Results and Insights

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#### Jeffrey M. Hausdorff, PhD

**Study Rationale:** Freezing of gait (FOG) is a poorly understood problem that markedly impairs the walking abilities and independence of about 60-80% of people who have Parkinson's disease (PD). The absence of a low-cost, objective way to accurately detect and quantify the occurrence of FOG curtails research and treatment of FOG. Pilot studies suggest that wearable devices (e.g., accelerometers) combined with machine learning algorithms have the potential to address this gap.

**Hypothesis:** We speculated that a machine learning contest, based on a relatively large, publicly accessible database of FOG events combined with accelerometer signals and accurate labels of the start and end of each FOG event, would empower AI experts from across the globe to develop new and better algorithms to automatically detect the occurrence of FOG from an accelerometer worn on the lower back of people who have PD and FOG.

**Study Design:** A 3-month machine learning contest was held on the Kaggle web-based platform. The competition ended with 10,133 registrations and 1,361 teams from 83 countries; 24,862 different solutions were submitted. The first-place solution detected FOG events accurately and precisely,

with few false positives and false negatives. Correlations between the gold standard reference and the first-place model predictions were high.

**Impact on Diagnosis/Treatment of Parkinson’s disease:** This positive experience demonstrates that machine learning contests can be used to introduce experts from AI to PD challenges and to harness their expertise in a relatively short period of time. Moreover, the results suggest that this approach can be used as a low-cost, objective way of detecting and quantifying FOG.

**Next Steps for Development:** When applied to acceleration signals collected in subjects who wore an accelerometer on their lower back continuously for 1 week, the new algorithm identified, for the first time, specific hours during the day when FOG peaked. Although follow-up confirmation studies are needed, these results appear to offer a means of quantifying FOG in “supervised”, clinical settings as well as in “unsupervised”, daily living settings and set the stage for the development and assessment of targeted interventions that could be applied to treat FOG and reduce its negative impact on health-related quality of life.

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**Alastair Noyce, MSc, MRCP, PhD, FHEA**

Professor of Neurology and Neuroepidemiology, Center for Preventive Neurology,  
Wolfson Institute of Population Health, Queen Mary University of London,  
Consultant Neurology, Barts Health NHS Trust

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Alastair Noyce, MSc, MRCP, PhD, FHEA, is a Professor in Neurology and Neuroepidemiology at the Centre for Preventive Neurology, Wolfson Institute of Population Health, Queen Mary University of London, and a Consultant Neurologist at Barts Health NHS Trust.

His research group at the CPN focuses on Parkinson's disease and other neurodegenerative disorders, particularly early identification and epidemiology, which includes environmental, clinical and genetic determinants. His group receives funding from Parkinson's UK, Cure Parkinson's, Barts Charity, The Michael J. Fox Foundation, Aligning Science Across Parkinson's and Innovate UK.

He leads the PREDICT-PD study and he is the Principal Investigator on the East London Parkinson's disease project. He is a steering committee member of the Global Parkinson's Genetics Program and leads a focus on the genetics of prodromal PD and the Training and Networking group. He is Chair of the International Parkinson and Movement Disorder Society Epidemiology Study Group, a member of the MDS prodromal sub-committee and the Early Onset PD Task Force, a member of the International RBD Study Group, and faculty for the MDS LEAP leadership program. He is Associate Editor of the Journal of Parkinson's Disease.

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## Abstract

### **The London-Dhaka Project — the Prevalence and Assessment of Cognitive Impairment in Parkinson's Disease**

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**Alastair Noyce, MSc, MRCP, PhD, FHEA; Prof Ahsan Habib; T. Zannat, KC. Dey, A. Zirra, ABSMS. Haque, E. Camboe, T. Haque, S. Waters, D. Mair, C. Marshall, AJ. Noyce**

**Study Rationale:** Cognitive impairment and dementia are feared complications of Parkinson's disease. Approximately half of patients have been diagnosed with dementia at 10 years from diagnosis with Parkinson's disease, but most studies predominantly include patients who are White and well-educated. Some studies suggest that cognitive impairment may be higher in certain ethnic groups.

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The aim of this study is to investigate the prevalence of cognitive impairment in a diverse group of patients with Parkinson's disease from East London (UK) and in Dhaka (Bangladesh). The study will compare standard instruments for assessing cognition with alternatives that might perform better in diverse patient groups or in patients who are not fluent in English.

**Hypothesis:** We aim to explore whether the prevalence of cognitive impairment in South Asian patients is higher than in White patients with PD, but that this difference is smaller than suggested by widely used cognitive tests such as the Montreal Cognitive Assessment.

**Study Design:** The London-Dhaka Parkinson's Cognition Study (LDPCS) is a cross-sectional, case-control study. Patients with a diagnosis of Parkinson's disease are recruited from movement disorder clinics at Barts Health NHS Trust (UK) and Bangabandhu Sheikh Mujib Medical University (Bangladesh), along with healthy individuals. The UK cohort represents a sub-group of the East London Parkinson Disease (ELPD) project.

At each site, we aim to recruit at least 200 new patients and 100 healthy controls over 2 years. Data collection includes clinical and demographic information, questionnaires, cognitive assessment tools (established and novel), neuropsychiatric assessment tools, and collection of samples for biomarkers.

**Impact on Diagnosis/Treatment of Parkinson's disease:** Studying cognitive impairment in diverse groups with Parkinson's disease will contribute to our overall understanding of Parkinson's dementia and how common it is. We believe that current assessment tools are not 'culturally fair' and over-estimate the prevalence of dementia in certain groups. Better tools for screening for cognitive impairment are needed and will inform clinical trial design.

**Next Steps for Development:** Over the next 15 months we will complete recruitment and analyze the results. We will report on the prevalence of dementia and make recommendations about the best tools to assess cognition. This will enhance clinical care and help design better clinical trials that enroll a diverse range of patients.

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## Nicole Polinski, PhD

Director, Preclinical Tools and Model Program, The Michael J. Fox Foundation

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Nicole Polinski, PhD, received her PhD in Neuroscience from Michigan State University investigating the impact of age on viral vector-mediated gene therapy for neurodegenerative diseases. Polinski serves as Director of the Preclinical Tools and Models Program at MJFF. Her current role includes managing the team at MJFF responsible for generating and distributing preclinical tools and models to the research community. This includes working with Parkinson's disease experts to identify gaps in the research tool space and designing tools to fill those gaps, managing 30+ business relationships, negotiating contracts and agreements, coordinating dozens of collaborations for tool generation/characterization, and leading the MJFF Industry Tools Consortium. In addition, Polinski assists with the Access Data and Biospecimens program serving as scientific support for the team. Within all of these roles, Polinski works to embody the MJFF principles of urgency, adaptability, collaboration and resourcefulness.

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## Abstract

### Resources Available Through the Michael J. Fox Foundation for Parkinson's Research

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**Nicole K. Polinski, Gloria Thakuria, Anna Schwartz, Elisia Clark, Josh Gottesman, Dave Alonso, Yasir Karim, Leslie Kirsch, Jamie Eberling**

For the past 23 years, The Michael J. Fox Foundation for Parkinson's Research (MJFF) has supported the Parkinson's disease (PD) research community by funding research in PD biology, biomarkers, and preclinical through clinical therapeutic developments. Over the past 15 years, MJFF has also expanded our role in the PD research space to provide non-financial resources to align the field and speed new discoveries and developments. These resources include (1) biosamples from a number of PD clinical studies, (2) clinical, genetic, biologic, and patient-reported outcome data from PD clinical studies, and (3) preclinical tools such as antibodies, proteins, cell lines, viral vectors, rodent models, etc. Herein we provide an overview of the many resources MJFF makes available to the research community, with details on how to browse and access resources that are currently available. We also highlight upcoming resources that are currently in development to provide insight into what will be available in the future. Finally, we provide information on how to contact MJFF to ask questions about existing resources, provide feedback and suggest additional resources MJFF could consider developing for the research community.

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## Tanya Simuni, MD, FAAN

Arthur C. Nielsen Jr. Professor of Neurology, Director, Movement Disorders Center,  
Northwestern University Feinberg School of Medicine

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Tanya Simuni, MD, FAAN, joined the faculty of the Northwestern University Feinberg School of Medicine in 2000 to build a multidisciplinary movement disorders center that is recognized by the Parkinson's Foundation, Huntington Disease Society of America and Wilson's Foundation as a Center of Excellence and serves as a training model in the region. She is the lead investigator of several clinical trials on experimental pharmacology, non-motor manifestations and pharmacological management of Parkinson's Disease (PD). She serves on several Steering Committees for the PD national clinical trials, several committees for PSG and the PF. She is the Site principal investigator (PI) and Steering Committee member for the largest PD biomarker initiative, Parkinson's Progression Markers Initiative (PPMI study), and site PI for the Network for Excellence in Neuroscience Clinical Trials (NEXT). Simuni is an active member of the American Academy of Neurology, American Neurological Association, the Movement Disorders Society as well as the Parkinson's Study Group.

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## Abstract

### Path to Prevention (P2P) Trial: Study Design and Status Update

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**Tanya Simuni, MD Christopher S. Coffey, PhD, Andrew Siderowf, MD, Caroline Tanner, MD, PhD, Sohini Chowdhury, Catherine Kopil, PhD, Todd Sherer, PhD, Michael Brumm, PhD, Karl Kieburtz, MD, Kimberly Fabrizio, Ben Saville, Cora Allen-Savietta, Barbara Wendelberger, Amy Crawford and Ken Marek, MD on behalf of the PPMI Investigators**

To describe the study design and proposed timeline of the first interventional study in Neuronal-Synuclein Disease (NSD).

**Background:** P2P is a platform, Phase 2 randomized double blind multi-center, multi-regimen clinical trial that is planned to evaluate the safety and early efficacy of investigational products for the treatment of biomarker-defined prodromal PD. Since the launch of the initiative, we have defined a new biological term Neuronal -Synuclein Disease (NSD) and plan to transition to the NSD stage-based inclusion criteria.

NSD is defined by presence of alpha-synuclein pathology, ultimately dopamine dysfunction, and stage dependent motor and non-motor clinical manifestations and related functional impairment. These participants were previously clinically defined as Parkinson's disease, Dementia with Lewy Bodies and Prodromal. The study is "nested" within the Parkinson's Progression Marker Initiative (PPMI) and sponsored by the MJFF.

**Methods:** P2P is a perpetual platform trial with a single Master Protocol dictating the conduct of the trial and regimen specific subprotocols outlining intervention specific aspects for each arm. Qualified participants will be recruited from the PPMI participants, based on NSD Stage 2B criteria defined by the presence of alpha-synuclein neuronal pathology (SAA in spinal fluid), dopaminergic dysfunction (DaTscan imaging) and clinical phenotype defined by presence of any of the following: Clinically detectable nonmotor/ subtle motor abnormalities but no functional impairment (Stage 2B).

The study's Multiple Primary Endpoints include 1) DAT imaging as measured by the rate of progression in the mean striatum Specific Binding Ratio (SBR) and 2) rate of progression in the MDS-UPDRS part III score. Secondary endpoints include safety, tolerability and feasibility. The study will have an array of exploratory clinical (including digital) and biomarker measures. Participants will first be randomized equally among all regimen-specific sub-protocols for which they are eligible. After randomization to a specific subprotocol, participants will be randomized to an active arm or placebo (N=125 per arm) in a K:1 ratio with K denoting the number of active interventions. Intervention duration will be at least 24 months (until the last participant in that regimen completes 24 months). The study is 82% powered to detect a slowing in either primary endpoint for each regimen, assuming a 20% slowing in DAT and a 35% slowing in MDS-UPDRS Part III.

**Results:** Interventions are being selected by a Therapeutic Evaluation Committee from > 15 industry submitted applications. The study targets to start enrolment in the first 2 regimens in 2025.

**Conclusion:** We report the design of the first platform interventional study targeting NSD Stage 2B population. Platform design allows efficiency of operational infrastructure, ability to share placebo arm and perpetual testing of the promising interventional candidates.



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**Diane Stephenson, PhD**

Executive Director, Critical Path Institute

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Diane Stephenson, PhD, is a neuroscientist by training with 30 years combined experience in academic neuroscience and drug discovery. She is passionate about translational science and has a long-time dedication to the discovery of therapies to treat diseases of the nervous system. Stephenson received her undergraduate degree in Biochemistry at the University of California and her PhD in Medical Neurobiology from Indiana University. She spent most of her career as a translational neuroscientist at the largest pharmaceutical companies focusing on disease areas including Alzheimer's, Parkinson's, Stroke, ALS and Autism Spectrum Disorders. Stephenson joined Critical Path Institute in 2011 and has launched several new programs with a focus on global collaborations to accelerate treatments for brain disorders. She presently leads Critical Path for Parkinson's (CPP), a multinational consortium comprised of academic experts, industry scientists, patient advocacy groups and regulatory experts collectively aimed at accelerating drug development tools for Parkinson's disease.

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## Abstract

### Aligning with Regulators to Advance Patient-Reported Outcome Assessments that are Fit-for-Purpose in Early-Stage Parkinson's Disease Clinical Trials

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**Sonya Eremenco, Diane Stephenson, PhD**

**Project Title:** Aligning with regulators to advance patient-reported outcome assessments that are fit-for-purpose in early-stage Parkinson's disease clinical trials

**Study Rationale:** There is a lack of clinical outcome assessments (COAs) consistent with U.S. FDA patient-focused drug development (PFDD) guidance for use as clinical trial endpoint measures in early-stage Parkinson's disease (PD). Aligning with regulatory agencies promises to streamline the path for acceptance of COAs to support endpoints in clinical trials

The Critical Path Institute's Clinical Outcome Assessment Program (COAP) has multiple examples of success in qualifying PRO measures including several in collaboration with academic experts across multiple disease areas.

This project focuses on leveraging existing qualitative data to identify concept(s) of interest for patient-reported outcome (PRO) measure development for early-stage PD.

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**Hypothesis:** Existing HealthMeasures item banks (e.g., PROMIS, Neuro-QoL) contain sufficient content and can be mapped to existing qualitative data to develop fit-for-purpose COAs for use in PD clinical trials.

**Study Design:** The Critical Path for Parkinson’s Digital Drug Development tool team in collaboration with University of Rochester CPP 3DT initiative has leveraged a case study called WATCH-PD aimed to advance the regulatory maturity of digital health technologies for early PD.

Qualitative patient-level interviews were carried out at FDA’s recommendation FDA and led to the generation of personal symptom maps that consist of both motor and nonmotor symptom domains bothersome to people with early-stage PD.

The C-Path team in collaboration with Northwestern University will carry out secondary qualitative analysis of WATCH-PD symptom maps (N=40) focusing on obtaining detail and to document and summarize key aspects of the selected concepts of interest (COI(s)) (frequency, intensity, degree of difficulty, etc.),

The above analyses will inform conceptual model development and item selection from HealthMeasures Item Banks.

**Impact on Diagnosis/Treatment of Parkinson’s disease:** This project aims to streamline the path to regulatory endorsement of COAs that align with FDA’s PFDD strategies. By collaborating with multidisciplinary stakeholders that include academic experts, clinicians, psychometricians, regulators and people with lived experience of PD, we will more efficiently develop COAs for use in PD clinical trials to evaluate clinical benefit of new treatments for early-stage PD.

**Next Steps for Development:** The present focus of the team is to review existing literature and the WATCH-PD personal symptom maps to identify concepts of interest that align with the HealthMeasures item bank.

# Poster Session

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John Streiff, PhD

AeroNeph Therapeutics

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## Abstract

### Hit-to-Lead STING Inhibitor Small Molecule Development for Parkinson's Disease

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Erik Schwiebert, PhD, John Streiff, PhD

**Study Rationale:** Stimulator of Interferon Genes (STING) is a compelling drug target for all forms of autoimmune disease and autoinflammation. Gain of function mutations in STING or other key proteins in this innate immunity signaling pathway cause rare or niche autoimmune syndromes. Armed with 6 different hit-to-lead chemical classes of STING inhibitors from a human cell-based high-throughput screening campaign on the 3 most common STING isoforms, we wished to determine if their biological and chemical profiles were amenable for development in Parkinson's disease (PD) 82.

**Hypothesis:** We hypothesized that one or more of our hit-to-lead STING inhibitor small molecules may have eventual therapeutic impact in PD by attenuating the chronic autoinflammation or neuroinflammation component of PD.

**Study Design:** We have profiled in multiple in vitro assays and panels 5 hit-to-lead STING inhibitor compound classes. One has progressed into a lead class category with the best permeability profile across human cell barrier, the best efficacy/potency in in vitro anti-inflammatory assays measuring type 1 interferons as biomarkers, and in other assays. More recently, in the Eurofins BioMAP systems biology platform, the 'best in class' compound for STING Inhibitor Class H showed robust anti-inflammatory and immune-modulatory profiles and its profile aligned closely with an autoimmune disease drug that is also used to suppress transplanted organ rejection.

**Impact on Diagnosis/Treatment of Parkinson's disease:** As mentioned in the Hypothesis statement, we predict that the optimal STING inhibitor identified out of our program will quell the chronic neuroinflammatory components of PD.

**Next Steps for Development:** In the final steps of our MJFF funded project, we are examining the pharmacokinetics of ANT H in escalating doses in mice to determine the dose that drives appearance of the drug in the cerebrospinal fluid and in brain tissue. If successful in terms of blood-brain barrier permeability, a PD mouse model study is planned and will be run on mice over-expressing mutant alpha-synuclein in the substantia nigra, with a full endpoint analysis including behavioral metrics.

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**Peter Vangheluwe, PhD**

KU Leuven

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Peter Vangheluwe, PhD, obtained his Master's degrees in bioscience engineering and cellular biotechnology at KU Leuven, Belgium, in 2000. He completed his PhD in Medical Sciences and performed his postdoctoral studies investigating ion transporters in various diseases. He received part of his training at the Membrane Protein Research Group, University of Alberta, Canada and in the P-type ATPase Centre of Excellence at University of Copenhagen, Denmark. He was appointed as assistant professor at KU Leuven in 2011, associate professor in 2016 and professor in 2020. Since 2012, he is head of the Laboratory of Cellular Transport Systems at KU Leuven and his lab has established ATP13A2 as a lysosomal polyamine transporter implicated in Parkinson's disease (PD). He currently investigates how a disturbed polyamine homeostasis contributes to PD and explores therapeutic strategies to correct polyamine imbalances. He's the lead investigator of the ASAP consortium IMPACT-PD studying the implications of disturbed polyamine and glucosylceramide transport in PD. He also actively engages in drug screening and development programs for modulators of polyamine and glucosylceramide transport for PD therapy.

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## Abstract

### The Lysosomal Polyamine Transporter ATP13A2, an Emerging Drug Target for Parkinson's Disease

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**Peter Vangheluwe, PhD**

**Study Rationale:** Polyamines are neuroprotective agents, and ATP13A2, one of the causative Parkinson's disease genes encodes for a lysosomal polyamine exporter. As such, ATP13A2 regulates cellular polyamine content and polyamine distribution between lysosomes and mitochondria. Conversely, ATP13A2 dysfunction leads to a reduced cellular polyamine content, accumulation of polyamines in lysosomes and shortage of polyamines in mitochondria, which contribute to lysosomal toxicity and mitochondrial oxidative stress.

**Hypothesis:** We hypothesize that altered plasma and brain polyamine levels may underline the early onset neuroinflammation symptoms in Atp13a2 KO mice. In addition, we hypothesize that ATP13A2 agonists may have therapeutic potential for PD.

**Study Design:** Brain and plasma polyamine levels in Atp13a2 KO mice are reduced prior to the onset of symptoms. In addition, supplementation of polyamines rescues disease phenotypes, whereas polyamine

deprivation exacerbates symptoms, showing that lower polyamine levels contribute to the manifestation of disease phenotypes. Furthermore, we have purified ATP13A2 and optimized a primary assay to screen for ATP13A2 agonists. We have performed the first high throughput screening on ATP13A2 providing proof of concept that ATP13A2 agonists can be identified for further clinical development.

**Impact on Diagnosis/Treatment of Parkinson's disease:** We will translate our findings obtained in Atp13a2 KO mice to patients and will determine whether plasma polyamine levels are reduced in patients with sporadic PD or in ATP13A2 carriers with neurodegeneration. In addition, ATP13A2 agonists may have therapeutic value for PD.

**Next Steps for Development:** A cohort of ATP13A2 carriers will be assembled for a clinical examination and collection of bio-samples for polyamine analysis in preparation of polyamine supplementation trials. Additional screening will take place to identify additional hit matter, which will enter a hit-to-lead cascade for the development of potent ATP13A2 agonists.



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## Dustin Watson

Director, Government Relations, The Michael J. Fox Foundation

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Dustin Watson is Director of Government Relations at The Michael J. Fox Foundation for Parkinson's Research. He is a registered lobbyist based in Washington, DC with thirty years of professional experience developing and managing legislative strategies on behalf of corporations, trade associations, foundations and nonprofit organizations at the local, state, national and international levels. Throughout his career, Watson has advocated for numerous public-interest causes and directed several grassroots campaigns in multiple states, while recruiting, training, and managing advocacy teams of government affairs and public policy staff, consultants and volunteers. He also supported the creation, launch and development of the Center for Business and Public Policy at Georgetown University's McDonough School of Business, secured millions of dollars in federal grants for nonprofit organizations, consulted on six congressional and state-based electoral campaigns, led business operations and federal lobbying services for a political consulting firm and directed government relations and public affairs for three trade associations.

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## Abstract

### The National Plan to End Parkinson's Act (H.R.2365/S.1064)

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## Dustin Watson

On Wednesday, March 29, 2023, the U.S. House of Representatives and U.S. Senate reintroduced the first-ever legislation solely devoted to ending Parkinson's disease. The bill was first introduced last Congress but did not come up for a vote by the time Congress adjourned at the end of its session in December 2022. With bipartisan support and nearly 150 total cosponsors in Congress, the National Plan to End Parkinson's Act (H.R.2365/S.1064) is no-cost legislation that will create an advisory council comprising members of federal agencies, people living with Parkinson's, care partners, researchers, clinicians and other non-federal experts. It also will alleviate financial and health burdens on American families and ensure those living with the disease have access to the care they need.

This bipartisan legislation is led by Senators Shelley Moore Capito (R-WV) and Chris Murphy (D-CT) and Representatives Gus Bilirakis (R-FL) and Paul Tonko (D-NY). The bill was introduced with the support of six additional senators and 12 additional representatives who signed on as cosponsors. A National Plan to End Parkinson's has the potential to dramatically increase federal research funding; develop more effective pathways for treatments and cures; improve early diagnosis; spark new and

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improved models for patient care; create standards and measures to prevent Parkinson's disease; address health disparities in diagnosis, treatment and clinical trial participation; and enhance public awareness of the disease.

The public-private advisory council created as part of this legislation will report to Congress on their progress and impact in ending Parkinson's. With the validation of a Parkinson's biomarker earlier this year, there is no better time for the federal government to get involved in supporting research to help find a cure.