

# Parkinson's Disease

*Research*

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## ***There Is Hope Through Research***

There are an estimated 10 million people living with PD worldwide, and an estimated 1 million people living with PD in the US, yet one of the most significant problems facing drug development for Parkinson's disease is low enrollment in research trials. Trial enrollment averages only 1 patient per month for most studies.

Research studies provide insight into better ways to care for us all. These studies are a team effort between the study doctors, nurses, coordinators, and patients who join studies.

For many people, taking part in a study is important because their participation is helping to make new treatments possible. Research studies are the key to finding new ways to prevent, diagnose and treat diseases.

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- **Early PD - Medication Naive (Not expected to require treatment for next 9 months)**
  - Neuraly - NLY01 (weekly subcutaneous injection)
- **Early PD - Medication Naive (In need of PD treatment)**
  - Cereval Therapeutics – TEMPO1
- **PD on Levodopa with motor fluctuations**
  - Cereval Therapeutics - TEMPO3
- **Moderately Advanced PD**
  - AskBio – GDNF PD
- **PD with levodopa induced dyskinesia**
  - Addex Pharma- ADX48621-301
- **PD GENERation Genetic Registry**
  - Parkinson's Foundation
- **Ohio State University Brain Bank & Biorepository**
  - Neuroscience Research Institute
- **PD with Sleep Impairment**
  - Light Therapy for PD (NeuroNEXT)
- **PD or ET with Planned DBS**
  - Abbott – ADROIT DBS Registry
  - Boston Scientific – Vercise DBS Registry
- **Any movement disorder**
  - OSU – Movement Disorders Registry

# Parkinson's Disease

## *Research – Early stage PD trials*

- NLY01-PD-1 study, also called the PRISM Parkinson's Research Study is a clinical research study focused on people with early stages of PD (disease onset within the past 5 years) who are not currently taking any PD medications to treat or manage symptoms.
  - This clinical research study is evaluating an investigational drug (NLY01) to determine if it might slow down the progression of Parkinson's disease. Patients who enroll in this study will receive the study drug weekly by subcutaneous injection over a period of 36 weeks.
- TEMPO-1 study is a clinical research study focused on people with early stages of PD (diagnosed within the past three years) who are not currently taking levodopa or dopamine agonists to treat or manage symptoms.
  - This clinical research study is evaluating an investigational drug (CVL-751/tavapadon) to see if it may improve PD symptoms that impact your movement and daily activities.
  - Upon completion of the study treatment period (27 weeks), you may have the option to participate in an open-label extension study (TEMPO- 4) to receive tevapadon for an additional 58 weeks.

# Parkinson's Disease

## *Research- Advanced Stage PD trials*

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- TEMPO-3 study is a clinical research study focused on people who currently taking oral Levodopa but are experiencing motor fluctuations during the daytime.
  - This clinical research study is evaluating an investigational drug (CVL-751/tavapadon) to see if it can further improve Parkinson's disease symptoms when taking levodopa.
  - Upon completion of the study treatment period (27 weeks), you may have the option to participate in an open-label extension study (TEMPO-4) to received tavapadon for an additional 58 weeks.
- ADX-48621-301 study is a clinical research study focused on people who have levodopa induced dyskinesia.
  - This clinical research study is aimed at determining the efficacy and safety of a study drug call dipraglurant (ADX-48621).
  - Upon completion of the 4 month long study, you may have the option to participate in an open-label extension study and receive dipraglurant for 12 months.

# Parkinson's Disease

## *Research- Advanced Stage PD trials*

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- GDNF PD study is a clinical research study focused on people who were officially diagnosed with PD at least 4 years ago and have moderately advanced symptoms.
  - This clinical research study is evaluating an investigational gene therapy (glial derived neurotrophic factor/GDNF) to assess its safety and tolerability. GDNF is also being tested to see if it can slow the progression of Parkinson's Disease.
  - The study lasts 5 years and involves undergoing surgery to deliver GDNF to a specific part of your brain. There are 15 visits required, mostly in the first 2 years.

# Parkinson's Disease

## *Research - Other options*

- **NeuroNext- NN110 study is focused on people with Parkinson's disease and impaired sleep.**
  - The purpose of this research study to find out if light therapy can help people with Parkinson's disease who experience difficulties with their sleep. We also want to find out if light therapy is safe and does not cause too many side effects.
  - Study participants will be provided a SunRay light box for light therapy.
- **PD GENERation is a genetic registry study whose aim is to create a genetic data and sample repository for Parkinson's disease and future research.**
  - Offers genetic counseling and testing for participants and requires two visits to our center.
- **NRI-BBB is a registry study that is established only at Ohio State and the Neuroscience Research Institute.**
  - The goal is to establish a state of the art tissue bank and biorepository at The Ohio State University to facilitate new research including clinical trials and biomarker discovery studies for neurological disease.
  - Involves no treatment and only one visit to collect samples.

# Parkinson's Disease

## *Research - Other options*

- ADROIT study is focused on people with Parkinson's disease or Essential tremor who have decided to receive DBS as part of their clinical care.
  - The purpose of this research study to collect post-market, long term safety and effectiveness information on people who are receiving the Abbott DBS system.
- Vercise study is focused on people with Parkinson's disease who have decided to receive DBS as part of their clinical care.
  - The purpose of this research study to collect post-market, long term safety and effectiveness information on people who are receiving the Boston Scientific DBS system.
- The Movement Disorders Registry is a registry study that is established only at Ohio State.
  - The goal is to collect clinical information that will help us study movement disorders and better understand how they progress and ways to treat them.
  - Involves no treatment and only information collected at your normal clinic appointments. You may be asked to complete some additional assessments.

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If you are interested in participating in a clinical trial, a physician and clinical research coordinator will screen you. If you are eligible for a trial, you will have access to some of the latest advances in Parkinson's disease treatment.

**Email: [PDRESEARCH@osumc.edu](mailto:PDRESEARCH@osumc.edu) for more information**