

# Parkinson's Disease Clinical Therapeutics Pipeline Program

## Request for Applications

- This funding program aims to accelerate clinical therapeutic development for Parkinson's disease treatment.
- Accepting pre-proposal applications on a rolling basis to allow for faster initial exchange with MJFF on proposed therapeutic ideas.
- Office hours available to address questions and partnerships after a full proposal invite.
- Only open to industry or industry + academia partnerships to foster clearer path to commercialization.



### BACKGROUND

Parkinson's disease (PD) affects nearly 1 million people in the US and over 6 million worldwide, with numbers expected to rise over the coming decades. PD is highly heterogeneous; individuals experience a wide array of motor and non-motor symptoms, many of which depend on disease severity and duration. Though our understanding of PD and its causes is growing, many questions remain. There are no drugs available that alter the progression of the disease, and current symptomatic treatments provide limited relief but come with complications and side effects.

The Michael J. Fox Foundation for Parkinson's Research (MJFF) is dedicated to finding a cure for Parkinson's disease (PD) through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson's today. Key to our mission is supporting the accelerated validation and de-risking of PD understanding into promising therapies. MJFF funding to date has fostered a robust pipeline that includes treatments for improved symptom management as well as those that may modify disease course. Beyond funding, additional resources such as research tools, open access data sets and connection to MJFF's broad network of scientists, clinicians and the patient community offer added opportunities to enable a program's success.



## PROGRAM GOAL

The Parkinson's Disease Therapeutics Pipeline Program advances clinical development of interventions by prioritizing scientifically robust studies that will accelerate progress towards the clinic and ultimately into patients' hands. Our strategic funding focuses on programs addressing unmet needs of people with PD with clear potential to prevent, stop, or delay disease progression or to reduce the burden of daily symptoms. As the requirements for delivering new treatments into the market depend on specialized expertise and resources, a unique goal of this program is to promote clearer paths to commercialization and market access by the PD community. Therefore, we are currently only accepting applications from industry groups or academic teams working in collaboration with a dedicated industry partner capable of further commercial development of a promising intervention.

When considering applications submitted to this program, MJFF prioritizes clinical programs that may reduce, slow or prevent disabling motor or non-motor symptoms of Parkinson's not well managed by current treatments. Activities within scope of this program include:

- **Clinical:** Progressing promising interventions with strong preclinical packages into/through initial clinical assessment exploring pharmacokinetics and pharmacodynamics, safety/tolerability, or early proof of clinical efficacy.

Any intervention may be considered based on clear patient need, rationale and strong mechanism-of-action understanding (e.g., pharmacological, biologic, gene therapy, surgical, non-invasive, non-pharmaceutical approaches). Applicants may also propose testing of repurposed or repositioned therapies that leverage robust biomarker-enabled testing strategies, or digital therapeutics targeting critical unmet needs and where market delivery and adoption barriers can be clearly addressed.

For this program, MJFF **will not consider** proposals focused on the following:

- Pre-clinical applications.
- Applications seeking to identify new intervention targets (e.g., large-scale screening or genomic/transcriptomic analyses).
- Applications testing tool compounds or biological manipulations with no viable path for further drug optimization/development.

Applicants interested in the above efforts should continue to monitor MJFF funding calls for future opportunities.

**If you are developing a therapy for people with Parkinson's disease and your program aligns with the Foundation's priorities described above, we want to hear from you.**

Please submit a pre-proposal via the [MJFF Grant Portal](#) to see if we are the right partner to help move your therapeutic ideas forward.



## PROGRAM PRIORITIES

When considering proposals submitted to this program, MJFF prioritizes those with the strongest preclinical-to-clinical translational potential, therapeutic rationale, and patient value, and that also fulfill the following criteria:

- The selected therapeutic target/pathway or mechanism shows a strong biological rationale to be pursued as a therapeutic target in PD.
- The proposal emphasizes a translational biomarker development plan (where applicable), including measures to monitor target engagement/modulation, hypothesized mechanism of action, and patient enrichment measures that can improve clinical trial design to de-risk further development.
- The proposal has a patient-centered approach incorporating patient voice in the clinical development plan.

In addition to approaches that may slow disease progression, MJFF has an interest in efforts that address moderate-to-advanced motor or non-motor symptoms such as advanced gait disturbances (e.g., balance issues linked to falls, freezing) and cognitive changes.



## FUNDING AVAILABLE

### **Duration:**

2 to 3 years for clinical programs

### **Award Amount:** \$250,000 - \$2,000,000

MJFF research grants aim to de-risk selected therapeutic programs leading to faster progress and results, as well as increased chances of attracting follow-on investment. MJFF prioritizes opportunities to complement and share the costs of therapeutic development with like-minded partners with a current or new commitment to PD. As such we have a flexible approach to funding translational and clinical work that is guided by novelty, the stage of development and the overall priority of the unmet medical need for people with PD. The scope and budget for your study will be discussed with MJFF staff if invited to submit a full proposal and should be commensurate with the ultimate work proposed. In general, award amounts for this program

may range from \$250,000 for smaller, targeted programs to \$2M for larger, multi-stage clinical programs.

Budgets include direct and indirect costs. For academic and for-profit institutions, no more than 15% or 10%, respectively, may go to indirect costs. Additional details about MJFF's indirect cost policy can be found in the [Application Guidelines](#) and [FAQ](#).



## DEADLINES & REVIEW SCHEDULE

The Parkinson's Disease Therapeutics Pipeline Program works in **two stages** with the goal of offering applicants frequent chances to propose promising therapeutics:

1. Applicants may **submit a pre-proposal application at any time** for initial consideration by MJFF within three weeks from submission. This stage is your first and best opportunity to determine if MJFF is the right partner for you.
2. Applicants whose pre-proposal is selected for further consideration **will be invited to submit a full proposal to an upcoming review cycle (see table below)** with at least six weeks of notice (unless otherwise discussed with the applicant). Invited applicants will have the opportunity to consult with MJFF on proposal development. Funding decisions will be communicated within three months of full proposal submission.

Applicants are permitted to submit multiple, unique therapeutic pre-proposals but should NOT submit multiple pre-proposals supporting different stages or aspects of the same therapeutic development program. Applicants are also permitted and encouraged to re-submit a revised pre-proposal that addresses prior feedback provided by MJFF, if applicable.

Invited Full Proposal Due Dates - 2023	Funding Decision Announced
July 27 <sup>th</sup> , 2023	November 2023

Note: We will continue to accept pre-proposals on a rolling basis. Stay tuned for the funding schedule for 2024.



## ELIGIBILITY

Applications may be submitted by researchers or clinicians at the following organization types:

- U.S. and non-U.S. biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities.
- U.S. and non-U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the

federal government in collaboration with biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities.

- MJFF encourages the inclusion of researchers who span career stages.
- Early career investigators (within 1-7 years of first independent appointment or equivalent) are encouraged to apply and are permitted to serve as Principal Investigator (PI); Post-doctoral fellows are permitted to serve as Co-Principal Investigator (Co-PI). Training and fellowship activities are not supported through this program.

## BIOSAMPLE REQUESTS

Investigators are encouraged to leverage MJFF-sponsored biospecimen and cell line collections for their studies. MJFF staff can assist with MJFF's biosample process at both the pre-proposal and full proposal stage. To review MJFF's available biosample collections, refer to the MJFF biorepository [website](#).

Investigators should indicate their intention to leverage MJFF's biosamples within their pre-proposal. If invited to submit a full proposal, a formal biosample request will be reviewed in parallel. Requests to access MJFF-sponsored biosample collection(s) without seeking MJFF funding support are welcome to apply through our Access to Biosamples and Data programs. Investigators should contact [resources@michaeljfox.org](mailto:resources@michaeljfox.org) to learn about the application process.



## DIVERSITY, EQUITY AND INCLUSION (DEI)

In pursuit of our mission to accelerate the development of better treatments and a cure for Parkinson's disease, MJFF aims to support a rigorous research agenda reflecting a wide and diverse range of perspectives on Parkinson's disease and carried out in diverse populations. Diversity may refer to characteristics including, but not limited to, race, religion, ethnicity, sex, gender identity, sexual orientation, socioeconomic circumstance, nationality, geographic background, ability and disability, political ideology and age. Parkinson's is a complex problem; the more angles from which we attack, the greater the chances of finding innovative scientific solutions to benefit everyone living with the disease. As such:

- The Foundation encourages applications from diverse investigators representing groups historically underrepresented in the research enterprise.
- Because research shows that diverse teams outperform homogeneous ones, we urge applicants to share information about the composition of the team that will carry out the funded work.
- Proposed work should seek wherever possible to include relevant diversity, such as inclusion of sex/gender in preclinical studies and inclusive recruitment in clinical studies.



## ADDITIONAL INFORMATION

The **Application Guidelines** provide general guidance on applying for funding from MJFF, though the Request for Applications always supersedes information contained in the Application Guidelines.

MJFF holds an **open access publication policy** requiring articles resulting from MJFF-funded work to be published initially in a preprint repository followed by an open access journal with free and immediate readership rights.

MJFF requires that the Principal Investigator be the primary applicant (i.e., the person who initiates and takes primary responsibility for the application). All application-related correspondence will be sent to the Principal Investigator.

If you are new to MJFF and would like to explore other partnership opportunities, please contact our Research Alliances team at [researchpartnerships@michaeljfox.org](mailto:researchpartnerships@michaeljfox.org) to learn more.

Thank you for your interest in collaborating with MJFF and your commitment to the Parkinson's community.